DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2013

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

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Printed for the use of the Committee on Appropriations

U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 2012

75–968

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2013

TUESDAY, MARCH 6, 2012.

BUDGET HEARING FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES—SECRETARY

WITNESS

HON. KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES

Mr. REHBERG. Madam Secretary, good afternoon, and welcome back to the House. Sorry we are late.

Before we begin our discussions about the Fiscal Year 2013 budget request, I want to raise a number of financial management issues related to HHH, including the more than $1.4 billion Anti-Deficiency Act violations submitted to Congress last July.

For those who may not be familiar with an Anti-Deficiency Act violation, the act and related funding statutes restrict in every possible way the expenditures, and expenses, and liabilities of the government so far as executive offices are concerned to specific appropriations for each fiscal year. In general, agencies that violate funding restrictions violate the Anti-Deficiency Act.

On July 14th, 2011, HHS notified Congress that it had identified 47 out of 176 contracts, slightly less than 30 percent, which had an ADA violation. These violations primarily related to a lack of applying general appropriations and contracting principles and laws properly.

This small identified violations in the HHS General Department Management Account, Agency for Health Care Research and Quality, the Centers for Disease Control, various components of the National Institutes of Health, and the Substance Abuse and Mental Health Services Agency.

The notice stated a substantial lack of understanding throughout the department of the legal limits on Federal contracts, in particular, contracts that required effort or deliverables over a period of several years.

The committee consulted with HHS Office of Inspector General, and understands one contributing cause is the lack of legal review of contracts, grants, and similar funding mechanisms throughout HHS. The violations seem to indicate either a fundamental misunderstanding of contract and appropriations principles, or deliberate disregard for the law.

A number of other improper financial management concerns have been raised recently. For example, a February 6th, 2012 joint letter to the Secretary from the Senate Finance Committee and House Committee on Ways and Means summarizes a number of issues supported in a recent independent audit by Ernst & Young on HHS' Fiscal Year 2011 financial statements. Some of the issues highlighted in this letter include Anti-Deficiency Act violations, so-called mystery money, funds that seem to disappear in the Fiscal 2011 financial audit, and HHS processes that date back to the 1980s.

These themes are certainly echoed on the July 14th, 2011 ADA notice to Congress. We understand the ADA violations date back to as far as 2002, and may go back several Administrations. However, blame is not the issue; it is accountability and corrective action.

Agencies must report and correct ADA violations according to Section 1351 of Title 31 of the U.S. Code. The agency shall report immediately to the President and Congress all relevant facts and a statement of actions taken. A copy of each report shall also be transmitted to the Comptroller General on the same date the report is transmitted to the President and Congress.

The agency must note if they suspect that the violations was knowing and willful, provide significant information on the appropriation or fund account for each violation, provide the name and position of the officers or employees responsible for the violation, and include all the facts pertaining to violation and action taken, including any new safeguards provided to prevent reoccurrence of the same type of violation.

The HHS notice from last July, however, asserts it will not take corrective adjustments to these accounts, that the HHS' own judgment are that these corrective adjustments would have serious programmatic repercussions. A self-determination of this magnitude by HHS is a precedent of unparalleled proportions, in my opinion.

The Comptroller General in 1937 once expressed the principle HHS and the Administration should follow, and it is equally applicable here. Where a payment is prohibited by law, the utmost good faith on the part of the officer, either in ignorance of the facts or in disregard of the fact, in purporting to authorize the incurring of an obligation, the payment of which is so prohibited, cannot take the case out of the statute. Otherwise, the purported good faith of an officer could be used to nullify the law.

We have consulted with GAO on the matter and understand that GAO advises agencies in these circumstances to adjust their accounts accordingly, and then, if they do not have enough budget authority to do so, they should report the ADA violation. They also advise agencies to record an obligation where they neglected to do so, and if they do not have enough budget authority to do so, report an ADA violation. If the impact of the violation results in programmatic shortfalls, HHS has an avenue to request funds to cover any shortfall through a supplemental or deficiency appropriation request in the notice.

Madam Secretary, I call upon HHS to go back and do everything it can to lawfully do to correct or mitigate the financial effects of the ADA violation, and make the appropriate adjustments. If a

supplemental or deficiency appropriation is needed, it should be requested. We cannot ignore the law and due process.

I am frustrated it took more than two years to report violations to Congress. This does not meet my definition of "immediate." The notice to the Comptroller General was even further delayed. It did not occur until after our committee contacted GAO to discuss the violations in September.

The requirement of naming the accountable is not in the notice. It is surprising that HHS' leadership does not hold itself accountable. Our citizens expect Federal agencies, especially the one that desires to run the Nation's health care system and hold others accountable with mandates, to stand up and identify an accountable party for each violation.

I was pleased HHS has updated some procedures and implemented one-time training for its contracting, finance, and budget personnel. Given the systematic and cultural entrenchment implied in the notice, HHS should ensure all senior officials get training. Further, I suggest HHS should require all contracts, grants, cooperative agreements, and similar actions to receive legal review, as suggested by the HHS OIG to ensure they do not violate ADA and other funding restrictions.

In addition, I believe HHS should have its OIG immediately and for the next several years conduct a statistically sample of all contracts, grants, and similar agreements, starting with Fiscal Year 2010, vehicles to ensure the training is effective and that no ADA or other funding restriction violations occur.

Madam Secretary, I would like an update within 30 days on the implementation strategies and status of these suggestions.

Finally, I understand Congress may expect another HHS ADA violation in the near future related to a pay restriction violation, and I do appreciate the advance notice. My understanding is the potential violation primarily impacts NIH as a limited number of employees were paid more than allowed by law. I look forward to a speedy notice with details to allow the committee more understanding on the issue.

I am, however, surprised the budget request does not include financial management corrective action initiatives, given the morass of issues. Therefore, Madam Secretary, I would like you to provide within 30 days a detailed 3-year corrective action initiative to rectify HHS's financial system and prevent ADA violations.

Please ensure the annual cost for operating division is identified for each year. The committee must be prepared to take steps to strengthen financial stewardship throughout HHS.

My desire was to start this hearing out on a more positive note. Unfortunately, our oversight and stewardship responsibility cannot be ignored. The confidence of the American public trust does matter.

I yield to my ranking member, Ms. DeLauro, for an opening statement.

Ms. DELAURO. Thank you very much, Mr. Chairman, and thank you all, and good afternoon. Let me thank the chairman for convening this important hearing.

I want to say a thank you to our witness today, Secretary Kathleen Sebelius. Madam Secretary, thank you once again for coming

before our subcommittee. Thank you for all of your hard work in implementing the Affordable Care Act, including the recently announced preventive measures for women to be covered without a co-pay. It is heartening to work with an Administration that understands and respects women's health needs.

I would just make a note that I think I am correct that the Anti-Deficiency Act violations that were reported occurred over a long period of time starting back in 2002, and I am sure what the Secretary will do is you will lay out for us the actions that you have taken to correct the underlying problems and make sure that similar violations do not happen again.

As we consider the President's budget proposal for 2013, we should also bear in mind the context in which it comes. These new proposals arrive after 2 consecutive rounds of budget cutting. Under the 2012 legislation enacted in December, appropriations for the Department of HHS are $3.4 billion less than the comparable level two years earlier. That is the cut in actual dollar terms without taking into account the rising costs, growing population, or unusually high levels of need.

Some very important programs and services have been cut: the Low Income Home Energy Assistance Program, or LIHEAP, has been reduced by $1.6 billion, almost one-third, between 2010 and 2012. This has happened at a time when heating oil prices are at record levels, other energy costs remain high, and the lingering effects of the recession leave many people still in need of help with their winter heating bills.

Another key priority is medical research at the NIH, the National Institutes of Health, to find better treatments and cures for diseases like cancer and Alzheimer's. While we were able to provide a modest increase for NIH in 2012, it was not enough to reverse the cut enacted for 2011. And due to the combination of reduced funding and rising costs, the number of research project grants made by the NIH is now at the lowest level since 2001.

For the Center for Disease Control, appropriations have been reduced by $735 million over the past two years, meaning cut backs in capacity to detect and control epidemics, and to reduce the prevalence and burden of both chronic and infectious diseases.

Programs that help to train doctors, nurses, and other health care providers have now taken a $90 million reduction since 2010. Mental health programs have been cut by about $50 million.

Yes, the Department of Health and Human Services has received additional funding through the Affordable Care Act for some of the programs that receive appropriations in this bill, though the ACA funding is not enough to make up for the loss in appropriations. But that funding was intended to supplement and expand funding for programs that increase the availability of health care and preventive services, not to simply allow equivalent cuts in regular appropriations.

And we are now facing the prospect of new rounds of much deeper cuts. There is the threat of sequestration under the Budget Control Act, which could mean an additional 8½ percent reduction in HHS appropriations for 2013.

We also hear that some on the majority side do not consider the current caps stringent enough, and want to use the budget resolu-

tion to reduce those limits still further. The contenders for the Republican presidential nomination seem to be trying to outdo each other with budget plans calling for huge, though mostly unspecified, future spending cuts. If any of these possibilities materialize, the past cuts I have been describing will look small by comparison.

So, that is the context for the 2013 budget we are discussing today, a proposal which involves a small further reduction in overall HHS appropriations. There are some good things in the proposal. For example, there is a $325 million increase for child care, a critical need for working families. There is also funding to meet the department's responsibilities in operating Medicare and implementing the Affordable Care Act. And there are small, but important, increases for food safety and control of health-care-acquired infections.

There are also some things in the President's budget that cause me concern. There is yet another reduction to LIHEAP, this one amounting to $452 million. There is a renewed proposal to cut the Community Service Block Grant almost in half, and there are additional rounds of cuts to the CDC, to mental health and substance abuse programs, and to the children's hospital graduate medical education and other health professions training programs. I very much hope that we will be able to find ways to alleviate and to avoid these reductions.

Secretary Sebelius, I look forward to your testimony and to a discussion of these and other issues.

Thank you, Mr. Chairman.

Mr. REHBERG. I understand that Mr. Rogers is coming, is going to want to make an opening statement. We will do it after the Secretary's testimony if he is here in time. Mr. Dicks.

Mr. DICKS. Should we wait until then?

Mr. REHBERG. Okay.

Mr. DICKS. Yeah. The only thing I wanted to say is welcome the Secretary here today. I would like to thank you for your help and giving attention to the Medicare geographic and disparity problem. I understand phase 2 of Institute of Medicine Study is due out in the spring. I hope that we will see some actionable recommendations on how to change the geographic adjusters to ensure they reflect accurate data and result in better access to care for seniors. I know we can count on you and your leadership in ensuring appropriate policies are implemented to resolve the geographic disparity issue.

And that is all I have, Mr. Chairman. I want to associate myself with the comments of the ranking member, Rosa DeLauro. And, you know, last year we were able to work out things. It started bad, but it came out pretty much okay. And I know we are concerned about this year's, but I am also very concerned about avoiding sequestration.

Thank you.

Mr. REHBERG. Thank you, Mr. Dicks. And, again, welcome, Secretary Sebelius. You may proceed.

Secretary SEBELIUS. Okay. That is on? Okay, thank you. That is why I asked.

OPENING STATEMENT

Thank you for having me here today. I just want to start by saying, Mr. Chairman, we share your concerns about the Anti-Deficiency Act violations. We did report them to you eight months ago. We have been working closely not only with our Office of Inspector General to retrain people and set up new procedures, but we are also working closely with the Government Accounting Office to put in place corrective action. I will be happy to submit a full report for your review, and want to assure you that although the grants were not structured appropriately, the dollars paid out were not in excess of the grant amounts. And we take this very seriously. We want to correct it in the future. It clearly was a process that has been underway for years. That is not an excuse, but to assure you that I will certainly respond.

The Budget before us today helps create an American economy built to last by strengthening our Nation's health care, supporting research that will lead to tomorrow's cures, and promoting an opportunity for America's children and families so everyone has a fair shot to reach their full potential. The Budget makes the investments that we need right now while reducing the deficit in the long term to make sure that the programs that millions of Americans rely on will be there for generations to come.

And I look forward to answering your questions about the Budget, but first I want to share some of the highlights.

The entire discretionary budget for our department is just under $77 billion, and this Committee oversees almost $70 billion of those dollars.

Over the last two years we have worked to deliver the benefits of the Affordable Care Act to the American people. Thanks to the law, more than 2 and a half million additional young Americans are already getting health coverage through their parents' plans. More than 25 million seniors have taken advantage of the free recommended preventive services under Medicare, and small business owners are getting tax breaks on their health care bills that allow them to hire more employees.

This year we will build on that progress by continuing to support states as they work to establish affordable insurance exchanges by 2014. Once these competitive marketplaces are in place, they will ensure that all Americans have access to quality, affordable health coverage.

Because we know that the lack of insurance is not the only obstacle to care, our Budget also invests in our health care workforce. The Budget supports training more than 7,100 primary care providers and placing them where they are needed most.

We also invest in America's network of community health centers. Together with fiscal year 2012 resources, our Budget creates more than 240 new access points for patient care, along with thousands of new jobs. All together, health centers will provide access to quality for 21 million people, 300,000 more than were served last year.

This Budget also continues our Administration's commitment to improving the quality and safety of care by wisely spending our health dollars. This means investing in health information tech-

nology. It also means funding the first of its kind CMS Innovation Center, which is partnering with physicians, nurses, hospitals, private payers, and others, who have accepted the challenge to develop a new sustainable health care system.

In addition, the HHS Budget ensures that 21st century America will continue to lead the world in biomedical research by maintaining funding for the National Institutes of Health. At the same time, the Budget recognizes the need to set priorities, make difficult tradeoffs, and ensure we use every dollar wisely. That starts with continuing support for President Obama's historic push to stamp out waste, fraud, and abuse in the health care system.

Over the last three years, every dollar we have put into health care fraud and abuse control has returned more than $7. Last year alone, these efforts recovered more than $4 billion, which is now in the Medicare Trust Fund and returned to Medicaid throughout the States. And last week, our Administration arrested the alleged head of the largest individual Medicare and Medicaid fraud operation in history. Our Budget builds on those efforts by giving law enforcement the technology and data to spot perpetrators early and prevent payments based on fraud from going out in the first place.

The Budget also contains more than $360 billion in health savings over 10 years, most of which comes from reforms to Medicare and Medicaid. These are significant, but they are carefully crafted to protect beneficiaries. For example, we have proposed significant savings in Medicare by reducing drug costs, a plan that also puts money back in the pockets of Medicare beneficiaries.

The Budget makes smart investments where they will have the biggest impact, and puts us all on a path to build a stronger, healthier, and more prosperous America for the future.

Thank you again, Mr. Chairman, and I look forward to our conversation.

[The information follows:]



STATEMENT OF

KATHLEEN SEBELIUS

SECRETARY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

THE PRESIDENT'S FISCAL YEAR 2013 BUDGET

BEFORE THE

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 6, 2012

Testimony of
Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
before the
United States House of Representatives
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Committee on Appropriations
March 6, 2012

Chairman Rehberg, Ranking Member DeLauro, and Members of the Subcommittee, thank you for the invitation to discuss the President's FY 2013 Budget for the Department of Health and Human Services (HHS).

The Budget for the Department of Health and Human Services (HHS) invests in health care, disease prevention, social services, and scientific research. HHS makes investments where they will have the greatest impact, build on the efforts of our partners, and lead to meaningful gains in health and opportunity for the American people.

The President's fiscal year (FY) 2013 Budget for HHS includes a reduction in discretionary funding for ongoing activities, and legislative proposals that would save an estimated $350.2 billion over ten years. The Budget totals $940.9 billion in outlays and proposes $76.7 billion in discretionary budget authority, including $69.6 billion under the purview of this Subcommittee. This funding will enable HHS to: Strengthen Health Care; Support American Families; Advance Scientific Knowledge and Innovation; Strengthen the Nation's Health and Human Service Infrastructure and Workforce; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Complete the Implementation of the Recovery Act.

STRENGTHEN HEALTH CARE

Delivering Benefits of the Affordable Care Act to the American People: The Affordable Care Act expands access to affordable health coverage to millions of Americans, increases consumer protections to ensure individuals have coverage when they need it most, and slows increases in health costs. Effective implementation of the Affordable Care Act is central to the improved fiscal outlook and well-being of the Nation. The Centers for Medicare & Medicaid Services (CMS) is requesting an additional $1 billion in discretionary funding to continue implementing the Affordable Care Act, including Affordable Insurance Exchanges, and to help keep up with the growth in the Medicare population.

Expand and Improve Health Insurance Coverage: Beginning in 2014, Affordable Insurance Exchanges will provide improved access to insurance coverage for millions of Americans. Exchanges will make purchasing private health insurance easier by providing eligible individuals and small businesses with one-stop shopping where they can compare benefit plans. New premium tax credits and reductions in cost-sharing will help ensure that eligible individuals can afford to pay for the cost of private coverage through Exchanges. FY 2013 will be a critical year for building the infrastructure and initiating the many business operations critical to enabling Exchanges to begin operation on January 1, 2014. The expansion of health insurance coverage for millions of low-income individuals who were previously not eligible for coverage also begins in 2014. CMS has worked closely with states to ensure they are prepared to meet the 2014 deadline and will continue this outreach in FY 2013.

Many important private market reforms have already gone into effect, providing new rights and benefits to consumers that are designed to put them in charge of their own health care. The Affordable Care Act's

Patient's Bill of Rights allows young adults to stay on their parents' plans until age 26 and ensures that consumers receive the care they need when they get sick and need it most by prohibiting rescissions and lifetime dollar limits on coverage for care, and beginning to phase out annual dollar limits. The new market reforms also guarantee independent reviews of coverage disputes. Temporary programs like the Early Retiree Reinsurance Plan (ERRP) and the Pre-Existing Condition Insurance Plan (PCIP) are supporting affordable coverage for individuals who often face difficulties obtaining private insurance in the current marketplace. Additionally, rate review and medical loss ratio (MLR) provisions helps ensure that health care premiums are kept reasonable and affordable year after year. The already operational rate review provision gives states additional resources to determine if a proposed health care premium increase is unreasonable and, in many cases, help enable state authorities to deny an unreasonable rate increase. HHS reviews large proposed increases in states that do not have effective rate review programs. The MLR provisions guarantee that, starting in 2011, insurance companies use at least 80 percent or 85 percent of premium revenue, depending on the market, to provide or improve health care for their customers or give them a rebate.

Strengthen the Delivery System: The Affordable Care Act established a Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center is tasked with developing, testing, and—for those that prove successful—expanding innovative payment and delivery system models to improve quality of care and reduce costs in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Since the Innovation Center began operations it has undertaken an ambitious agenda encompassing patient safety, coordination of care among multiple providers, and enhanced primary care. These projects can serve as crucial stepping stones towards a higher-quality, more efficient health care system.

Ensuring Access to Quality Care for Vulnerable Populations: Health Centers are a key component of the Nation's health care safety net. The President's Budget includes a total of $3 billion, including an increase of $300 million from mandatory funds under the Affordable Care Act, to the Health Centers program. This investment will provide Americans in underserved areas, both rural and urban, with access to comprehensive primary and preventive health care services. Together with 2012 resources, HHS' budget will create more than 240 new access points for patient care. Overall, HHS' investment in health centers will provide access to quality care for 21 million people, an increase of 300,000 additional patients over FY 2012. The Budget also promotes a policy of steady and sustainable health center growth by distributing Affordable Care Act resources over the long-term. This policy safeguards resources for new and existing health centers to continue services and ensures a smooth transition as health centers increase their capacity to provide care as access to insurance coverage expands.

Improving Healthcare Quality and Patient Safety: The Affordable Care Act directed HHS to develop a national strategy to improve health care services delivery, patient health outcomes, and population health. In FY 2011, HHS released the National Strategy for Quality Improvement in Health Care, which highlights three broad aims: Better Care, Healthy People and Communities, and Affordable Care. Since publishing the Strategy, HHS has focused on gathering additional input from private partners and aligning new and existing HHS activities with the Strategy. HHS will enhance the Strategy by incorporating input from stakeholders and developing metrics to measure progress toward achieving the Strategy's aims and priorities. Already, the Strategy is serving as a blueprint for quality improvement activities across the country.

Investing in Innovation: HHS is committed to advancing the use of health information technology (health IT). The Budget includes $66 million, an increase of $5 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate the adoption of health IT and promote electronic health records (EHRs) as tools to improve both the health of individuals and the health care system as a whole. The increase will allow ONC to provide more assistance to health care providers

as they become meaningful users of health IT. Furthermore, through the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act, CMS is providing hospitals and medical professionals who participate in Medicare and Medicaid with substantial incentive payments for the adoption and meaningful use of EHRs. As of February 1, CMS had made incentive payments to more than 23,600 providers who have met the objectives for meaningful use in the Medicare EHR Incentive Program and more than 19,600 providers who have adopted, implemented, or upgraded EHRs, or met meaningful use objectives in the Medicaid EHR Incentive Program. By encouraging providers to modernize their systems, this investment will improve the quality of care and protect patient safety.

SUPPORT AMERICAN FAMILIES

Healthy Development of Children and Families: HHS oversees many programs that support children and families. The FY 2013 Budget request invests in early education, recognizing the role high-quality early education programs can play in preparing children for school success.

Investing in Education by Supporting an Early Learning Reform Agenda: The FY 2013 Budget supports critical reforms in Head Start and a Child Care quality initiative that, when taken together with the Race to the Top Early Learning Challenge, are key elements of the Administration's broader education reform agenda designed to improve our Nation's competitiveness by helping every child enter school ready for success.

On November 8, 2011 the President announced important new steps to improve the quality of services and accountability at Head Start centers across the country. The Budget requests over $8 billion for Head Start programs, an increase of $85 million over FY 2012, to maintain services for the 962,000 children currently participating in the program. This investment will also provide resources to effectively implement new regulations that require grantees that do not meet high quality benchmarks to compete for continued funding, introducing an unprecedented level of accountability into the Head Start program. By directing taxpayer dollars to programs that offer high-quality Head Start services, this robust, open competition for Head Start funding will help to ensure that Head Start programs provide the best available early education services to our most vulnerable children.

The Budget includes $300 million for a new child care quality initiative that states would use to invest directly in programs and teachers so that individual child care programs can do a better job of meeting the early learning and care needs of children and families. The funds would also support efforts to measure the quality of individual child care programs through a rating system or another system of quality indicators, and to clearly communicate program-specific information to parents so they can make informed choices for their families. These investments are consistent with the broader reauthorization principles outlined in the Budget, which encompass a reform agenda that would help transform the Nation's child care system to one that is focused on continuous quality improvement and provides more low-income children access to high-quality early education settings that support children's learning, development, and success in school.

Keeping America Healthy: The President's Budget includes resources necessary to enhance clinical and community prevention, support research, develop the public health workforce, control infectious diseases, and invest in prevention and management of chronic diseases and conditions.

Tobacco Prevention Activities: Tobacco use kills an estimated 443,000 people in the United States each year. Despite progress in reducing tobacco use, 1 in 5 high school students and adults continue to smoke, costing our Nation $96 billion in medical costs and $97 billion in lost productivity each year. The Budget includes $586 million in funding from the Centers for Disease Control and Prevention (CDC), the

National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to further help reduce smoking among teens and adults and support research on preventing tobacco use, understanding the basic science of the consequences of tobacco use, and improving treatments for tobacco-related illnesses. HHS is striving to reduce adults' annual cigarette consumption in the United States from 1,281 cigarettes per capita to 1,062 cigarettes per capita by 2013.

Million Hearts Initiative: The Million Hearts Initiative is a national public-private initiative aimed at preventing 1 million heart attacks and strokes over 5 years, from 2012 to 2017. It seeks to reduce the number of people who need treatment and improve the quality of treatment that is available. It focuses on increasing the number of Americans who have their high blood pressure and high cholesterol under control, reducing the number of people who smoke, and reducing the average intake of sodium and trans fats. To achieve this overall goal, the Initiative will promote medication management and support a network of electronic health record registries to track blood pressure and cholesterol control, along with many other public-private collaborations. In FY 2013, the Budget requests $5 million for CDC to achieve measurable outcomes in these areas.

Preventing Teen Pregnancy: The Budget includes $105 million for the Office of the Assistant Secretary for Health for teen pregnancy prevention programs. These programs will support community-based efforts to reduce teen pregnancy using evidence-based models and promising programs needing further evaluation. The Budget also includes $15 million in funding for CDC teen pregnancy prevention activities to reduce the number of unintended pregnancies through science-based prevention approaches. Additionally, the Budget would repurpose unobligated funds to create a new teen pregnancy prevention program specifically targeted to youth in foster care, who are at particularly high risk of becoming teen parents.

Protect Vulnerable Populations: HHS is committed to ensuring that vulnerable populations continue to receive critical services during this period of economic uncertainty. For example, the ACF Budget requests includes a $7 million increase in funding for the Family Violence Prevention programs in order to expand shelter capacity and services and to support higher call volume to the Domestic Violence Hotline.

Preventing and Treating HIV/AIDS: The FY 2013 Budget includes $3.3 billion for domestic HIV/AIDS activities to increase the availability of treatment to people living with HIV/AIDS in the United States, improve adherence to medications, and support prevention programs in states and communities. This total investment includes $1 billion, an increase of $67 million, to increase access to life-saving treatments through the AIDS Drug Assistance Program, and $236 million, an increase of $20 million, to support care provided by HIV clinics across the country.

This total also includes $826 million for CDC's domestic HIV/AIDS prevention activities, an increase of $40 million above FY 2012, to support grants to health departments to reduce new HIV infections, identify previously unrecognized HIV infections, and improve health outcomes. In addition, funds will support research, surveillance, evaluation, and implementation of high-impact prevention programs among HIV-affected populations. In FY 2013, CDC will award grants to 69 state and local health departments to implement HIV/AIDS prevention programs according to a revised funding algorithm instituted in FY 2012, which better aligns the distribution of prevention resources with the disease burden rather than with historical AIDS data. CDC will also support up to 36 jurisdictions for an expanded testing initiative to focus on groups at highest risk for acquiring HIV such as men who have sex with men, African Americans, and injection drug users.

Refugee Transitional and Medical Services: The Budget requests $805 million to provide time-limited cash and medical assistance to newly arrived refugees, helping them become self-sufficient as quickly as

possible, and to provide shelter for unaccompanied alien children until they can be placed with relatives or other sponsors, repatriated to their home countries, or receive relief under U.S. immigration law. Additional funding will primarily cover rising medical costs—many refugees have spent their lives in camps where medical care is limited or non-existent—and serve the growing number of unaccompanied alien children made eligible for benefits under the Trafficking Victims Protection Reauthorization Act of 2008.

Elder Justice: The Budget includes $43 million for the Administration on Aging (AoA) to address the growing problem of elder abuse, neglect, and exploitation which affects more than 5 million seniors annually. Research indicates that older victims of even modest forms of abuse have dramatically higher morbidity and mortality rates than non-abused older people. To combat this abuse, the Budget provides $8 million for newly-authorized Adult Protective Services Demonstration grants, along with $9 million in ongoing funding for state grants to raise awareness of elder abuse and neglect and for resource centers and related activities that support nationwide elder rights activities. The Budget also includes $17 million for the Long-term Care Ombudsman Program to improve the quality of care for the residents of long-term care facilities by resolving complaints on behalf of residents.

Keeping People in Communities: Part of HHS' strategic plan includes enabling seniors to remain in their own homes with a high-quality of life for as long as possible through the provision of home and community-based services, including supports for family caregivers. Some seniors, if unable to remain independent in the community, will be forced to move into a nursing home at a significant potential cost to Medicaid. The Budget includes $1.4 billion in AoA to help seniors stay in their homes through Home and Community-Based Supportive Services, Senior Nutrition Programs, and Caregiver Support programs. The Budget also proposes to transfer the Senior Community Service Employment Program from the Department of Labor to the Administration on Aging. This move provides greater alignment with the agencies that provide supportive services.

Community Services Programs: The Budget includes $400 million for Community Services programs. This funding level includes $350 million for the Community Services Block Grant, and proposes to use a system of standards and competition to target the funds to high-performing agencies that are most successful in meeting community needs. In support of the Healthy Food Financing Initiative, $10 million is available to fund community development corporations to eliminate food deserts by improving access to grocery stores, farmers' markets, and other venues for healthy, affordable groceries. Additionally, $20 million is requested for the Community Economic Development program to sponsor enterprises providing employment, training, and business development opportunities for low-income Americans.

Vulnerable Youth: The ACF Budget includes an additional $5 million as part of a cross–agency effort to identify and test new ways to strengthen services for disconnected youth—14- to 24-year-olds who are neither working nor in school. This $5 million will be utilized in close cooperation with an additional $5 million requested by the Department of Education and $10 million from the Department of Labor. In addition to the funding request, the Administration proposes a general provision in the appropriations act to support a limited number of "performance partnerships" that would provide states and localities with enhanced flexibility in determining how services are structured in return for strong accountability for results.

Reduce Foodborne Illness: The Budget reflects the Administration's commitment to transforming our Nation's food safety system into one that is stronger and that reduces foodborne illness and includes an increase of $17 million above FY 2012 to support CDC's role in implementing the Food Safety and Modernization Act. HHS will continue to modernize and implement a prevention-focused domestic and import safety system. Collaboratively, FDA and CDC are working to decrease the rate of Salmonella Enteritidis illness in the population from 2.6 cases per 100,000 to 2.1 cases per 100,000 by December

2013. In FY 2013, CDC will enhance surveillance systems and designate five Integrated Food Safety Centers of Excellence at state health departments.

ADVANCE SCIENTIFIC KNOWLEDGE AND INNOVATION

Biomedical and Behavioral Research: The FY 2013 Budget maintains funding for the NIH at the FY 2012 level of $30.9 billion, reflecting the Administration's priority to invest in innovative biomedical and behavioral research that spurs economic growth while advancing medical science to improve health. NIH is generating discoveries that are opening new avenues for disease treatment and prevention and revolutionizing patient care. In FY 2013, NIH will seek to take advantage of such discoveries by investing in basic research on the fundamental causes and mechanisms of disease, accelerating discovery through new technologies, advancing translational sciences, and encouraging new investigators and new ideas.

National Center for Advancing Translational Sciences: In FY 2013, NIH will continue to implement the new National Center for Advancing Translational Sciences (NCATS), established in FY 2012, in order to re-engineer the process of translating scientific discoveries into new medical products. Working closely with partners in the regulatory, academic, nonprofit, and private sectors while not duplicating work going on in the private sector, NCATS will strive to identify innovative solutions to overcome hurdles that slow the development of effective treatments and cures. A total of $639 million is proposed for NCATS in FY 2013, including $50 million for the Cures Acceleration Network.

Medical Countermeasure Development: The HHS Medical Countermeasure Enterprise includes initiatives across the Department covering the spectrum of medical countermeasure development, from early biological research to stockpiling of approved products. The FY 2013 Budget includes $547 million for the Biomedical Advanced Research and Development Authority, an increase of $132 million over FY 2012, to develop and improve next-generation medical countermeasures (MCM) in response to potential chemical, biological, radiological, and nuclear threats. The Budget also provides $50 million to establish a strategic investment corporation that would function as a public-private venture capital fund providing companies developing MCMs with the necessary financial capital and business acumen to improve the chances of successful development of new MCM technologies and products. Together, these investments will provide HHS with new tools to enhance the success of medical countermeasure development.

Enhancing Health Care Decision-Making: The HHS Budget includes $599 million for research that compares the risk, benefits, and effectiveness of different medical treatments and strategies, including health care delivery, medical devices, and drugs, including $78 million from the Patient-Centered Outcomes Research Trust Fund established by the Affordable Care Act. Evidence generated through this research is intended to help patients make informed health care decisions that best meet their needs. This level of funding will primarily support research conducted by NIH, core research activities within the Agency for Healthcare Research and Quality (AHRQ), and data capacity activities within the Office of the Secretary. Resources from the Trust Fund will support comparative clinical effectiveness research dissemination, improved research infrastructure, and training of patient-centered outcomes researchers. HHS core research will be coordinated to complement projects supported through the Trust Fund and through the independent Patient-Centered Outcomes Research Institute.

STRENGTHEN THE NATION'S HEALTH AND HUMAN SERVICE INFRASTRUCTURE AND WORK FORCE

Investing in Infrastructure: A strong health workforce is key to ensuring that more Americans can get the quality care they need to stay healthy. The Budget includes $677 million, an increase of $49 million over FY 2012, within HRSA to expand the capacity and improve the training and distribution of primary

care, dental, and pediatric health providers. The Budget will support the placement of more than 7,100 primary care providers in underserved areas and begin investments that expand the capacity of institutions to train 2,800 additional primary care providers over 5 years.

The FY 2013 Budget also supports state and local capacity for core public health functions. Within the Prevention Fund allocation, CDC will invest $20 million in new activities to coordinate with public health laboratories to improve efficiency through proven models, such as regionalizing testing in multi-state laboratories. To ensure an effective public health workforce, the Budget requests $61 million, of which $25 million is through the Prevention Fund, for the CDC public health workforce to increase the number of trained public health professionals in the field. CDC's experiential fellowships and training programs create a prepared and sustainable health workforce to meet emerging public health challenges. In addition, the Budget requests $40 million in the Prevention Fund to maintain support for CDC's Public Health Infrastructure Program. This program will assist health departments in meeting national public health standards and will increase the capacity and ability of health departments in areas such as information technology and data systems, workforce training, and regulation and policy development.

INCREASE EFFICIENCY, TRANSPARENCY, AND ACCOUNTABILITY OF HHS PROGRAMS

Living Within our Means: HHS is committed to improving the Nation's health and well-being while simultaneously contributing to deficit reduction. The FY 2013 discretionary request demonstrates this commitment by maintaining ongoing investments in areas most central to advancing the HHS mission while making reductions to lower priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the FY 2013 request includes over $2.1 billion in terminations and reductions to fund initiatives while achieving savings in a constrained fiscal environment. Many of these reductions, such as the $177 million cut to the Children's Hospital Graduate Medical Education Payment Program, the $327 million cut to Community Services Block Grants, and the $452 million cut to the Low Income Home Energy Assistance Program (LIHEAP) were very difficult to make, but are necessitated by the current fiscal environment.

Regarding LIHEAP, the Administration proposes to adjust funding for expected winter fuel costs and to target funds to those most in need. The request is $3 billion, $452 million below the FY 2012 level and $450 million above both FY 2008 and the 2012 request. With constrained resources, the Budget targets assistance where it is needed most. The request targets $2.8 billion in base grants using the state allocation Congress enacted for FY 2012. The request also includes $200 million in contingency funds, which will be used to address the needs of households reliant on home delivered fuels (heating oil and propane) should expected price trends be realized, as well as other energy-related emergencies.

In September 2011, the Administration detailed a plan for economic growth and deficit reduction. The FY 2013 Budget follows this blueprint in its legislative proposals, presenting a package of health savings proposals that would save more than $360 billion over 10 years, with almost all of these savings coming from Medicare and Medicaid. Medicare proposals would encourage high-quality, efficient care, increase the availability of generic drugs and biologics, and implement structural reforms to encourage beneficiaries to seek value in their health care choices. The Budget also seeks to make Medicaid more flexible, efficient, and accountable while strengthening Medicaid program integrity. Together, the FY 2013 discretionary budget request and these legislative proposals allow HHS to support the Administration's challenging yet complementary goals of investing in the future and establishing a sustainable fiscal outlook.

Program Integrity and Oversight: The FY 2013 Budget continues to make program integrity a top priority. The Budget includes $610 million in discretionary funding for Health Care Fraud and Abuse

Control (HCFAC), the full amount authorized under the Budget Control Act of 2011 (BCA). The Budget also proposes to fully fund discretionary program integrity initiatives at $581 million in FY 2012, consistent with the BCA. The discretionary investment supports the continued reduction of the Medicare fee-for-service improper payment rate; investments in prevention-focused, data-driven initiatives like predictive modeling; and HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiatives, including Medicare Strike Force teams and fighting pharmaceutical fraud.

From 1997 to 2011, HCFAC programs have returned over $20.6 billion to the Medicare Trust Funds, and the current three-year return-on-investment of 7.2 to 1 is the highest in the history of the HCFAC program. Last year these efforts recovered more than $4 billion. The Budget proposes a 10-year discretionary investment yielding a conservative estimate of $11.3 billion in Medicare and Medicaid savings and 16 program integrity proposals to build on the Affordable Care Act's comprehensive fraud fighting authorities for savings of an additional $3.6 billion over 10 years.

Additionally, the Budget includes funding increases for significant oversight activities. The request includes $84 million for the Office of Medicare Hearings and Appeals, an increase of $12 million, to continue to process the increasing number of administrative law judge appeals within the statutory 90-day timeframe while maintaining the quality and accuracy of its decisions. The Budget also includes $370 million in discretionary and mandatory funding for the Office of Inspector General (OIG), a 4 percent increase from FY 2012. This increase will enable OIG to expand CMS Program Integrity efforts in areas such as HEAT, improper payments, and focus on investigative efforts on civil fraud, oversight of grants, and the operation of new Affordable Care Act programs.

Additionally, Durable Medical Equipment (DME) Competitive Bidding is providing competitive pricing, while continuing to ensure access to quality medical equipment from accredited suppliers, which will save Medicare $25.7 billion over 10 years and help millions of Medicare beneficiaries save $17.1 billion in out-of-pocket costs over 10 years. The Budget proposes to extend some of the efficiencies of DME Competitive Bidding to Medicaid by limiting Federal reimbursement on certain DME services to what Medicare would have paid in the same state for the same services. This proposal is expected to save Medicaid $3.0 billion over 10 years.

Consolidate and Improve Activities Related to Prevention and Behavioral Health: The Budget includes $500 million within SAMHSA for new, expanded, and refocused substance abuse prevention and mental health promotion grants to states and tribes. To maximize the efficiency and effectiveness of its resources, SAMHSA will use competitive grants to identify and test innovative prevention practices and will leverage state and tribal investments to foster widespread implementation of evidence-based prevention strategies.

The Budget also consolidates funding for initiatives aimed at addressing chronic disease prevention. Chronic diseases and injuries represent the major causes of morbidity, disability, and premature death and heavily contribute to the growth in health care costs. The Budget aims to improve the health of individuals by focusing on prevention of chronic diseases and injuries rather than focusing solely on treating conditions that could have been prevented. Specifically, the Budget allocates $379 million, an increase of $129 million over FY 2012, to a new integrated grant program in CDC that refocuses disease-specific grants into a comprehensive program that will enable health departments to implement the most effective strategies to address these leading causes of death. Because many inter-related chronic disease conditions share common risk factors, the new program will improve health outcomes by coordinating the interventions that can reduce the burden of chronic disease.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

SECTION 220

Mr. REHBERG. Great. Thank you very much. We will begin our questioning then at this time.

And, Madam Secretary, Section 220 of the Fiscal 2012 omnibus requires reasonable transparency and sharing of information with the public through a website on how the $1 billion prevention and public health fund will be awarded and spent. In the 2011 State of the Union, the President said, "In the coming year, we will also work to rebuild people's faith in the institution of government. Because you deserve to know exactly how and where your tax dollars are being spent, you'll be able to go to the website, get that information for the first time in history."

In fact, in the Fiscal Year 2012 omnibus, signed into law by the President on December 23rd of 2011, it included a provision making this promise a reality. I was quite surprised to note, however, that the President's Fiscal Year 2013 budget proposes to eliminate a reasonable transparency requirement for the Prevention and Public Health Fund. The request would remove Section 220 in its entirety.

How does eliminating the public reporting website fulfill the President's commitment to transparency? In my mind, it does just the opposite. Can you help us understand the policy behind this proposal?

Secretary SEBELIUS. Well, Mr. President—I mean, sorry, Mr. Chairman.

Mr. REHBERG. That is okay. [Laughter.]

Not yet.

Secretary SEBELIUS. It is not typical for an Administration Budget to give ourselves direction of how to report. I can tell you that we take transparency very seriously. That is why this morning the website recommended in the last year's fiscal year 2012 Budget is up and running, and so you will be able to go to the website and see very clearly where tax dollars are being spent. We eliminated the reporting requirement, but fully intend to comply with the website for ongoing budgets.

BUDGET RESOURCES AND PUBLIC HEALTH

Mr. REHBERG. Okay. The President's request appears to make a policy shift from supporting using discretionary funds for traditional public health programs in favor of what I would call health access programs. For example, the President reduces the Centers for Disease Control by the $668 million, while increasing the Centers for Medicare and Medicaid by $1 billion to implement exchanges.

Although the CDC does get increases from other resources, like the Public and Prevention Health Fund, an evaluation set-aside, such that the total program level is only a reduction of $222 million, these reductions are all primarily from public health programs.

Another interesting observation I make regarding the President's request is that what appears to be a cut in a number of programs that provide support for children, women, and minority populations. For example, the following programs all reflect reduced

funding in the President's budget: CDC's birth defects, development, disability and health programs, HHS's Office of Minority Health, HHS's Office of Women's Health, HHS' Office of Civil Rights, elimination of the racial and ethical approaches to community health at CDC, and an unanticipated reduction in NIH's National Children's Health Study, Children, Youth, Women, and Families HIV/AIDS programs. Please explain your apparent disproportional shift from women, children, and minority programs and the anticipated impact. I assume you believe the request provides sufficient support to public health activities, but please describe what public health factors you considered in deciding on the appropriate level of resources to shift out of public health.

Secretary SEBELIUS. Well, Mr. Chairman, as you know, this is a challenging budget atmosphere. The President requested all of his Cabinet officers to make strategic choices and determine the best use of our resources. I can assure you that there is no reduction in our interest in women, children, and minority health programs. In fact, I can assure this Committee that more activity and more focus has been directed toward these programs in the last three years than probably in the last several decades.

What we have done is ask each of our agency directors, including Dr. Frieden at the Centers for Disease Control and Prevention, my Assistant Secretary on Health, and other leaders to identify program duplication ideas, to efficiently reach the population served, and flexibility to States so they can address the target populations. In a number of the cases that you mentioned, we are eliminating programs that either sat on top of others or did not allow the effective use of resources.

The Budget includes increases in a whole variety of programs aimed at children and families. The Budget increased child care programs by $825 million so that the numbers are increasing. HRSA health centers are increasing their output to sites and providers so that we will serve additional women, children, and families. The CDC vaccines for children program is increased. The IHS program, which actually serves some of the most vulnerable families in the country, is increased—the Agency for Children and Family Head Start Program. So, we are trying to be strategic and trying to use our resources as efficiently as possible.

Mr. REHBERG. Thank you. I will try and hold pretty tight on the time, myself included. And so, I apologize if I gavel you all down or you, Secretary Sebelius. But just so everybody gets a fair shot.

Thank you, Ms. DeLauro. And, Mr. Rogers, if you would like to give an opening statement.

MANDATORY SPENDING

Mr. ROGERS. Thank you, Mr. Chairman. I apologize for being tardy.

Madam Secretary, welcome.

Secretary SEBELIUS. Thank you, Mr. Chairman.

Mr. ROGERS. This is truly a historic time in our country's history. I do not have to tell you that we are borrowing 40 cents on every dollar we spend. But it is high time, and the people have told us this. It is high time that we get serious about reducing spending for the debt and the record-setting deficit that we are running

every year, now four years running, of the trillion dollars plus, running our debt now to some $16 trillion.

Fully 89 percent of your budget is mandatory spending. Of the total budget that you have proposed, $604.4 billion, the mandatory portion of that is 89 percent, which is outside the jurisdiction of this committee, subcommittee. It is automatic spending that comes out of the Treasury whether we act or not.

I think the onus is on the Administration to tell us how we can stabilize these out of control entitlement programs. I see an old proposal in your budget request to put some sort of discipline on the wildly growing mandatory side of the budget.

We have known about these shortcomings for years now, and yet on top of this spending sits the President's controversial health care law. Regardless of whether you support or oppose the Affordable Care Act—many Americans do not—the reality is Obamacare is a budget buster. The CBO has reported that this law will cost billions more than we were told when we voted two years ago, but I will not be surprised to see even these ominous estimates skyrocket once the rosy assumptions utilized by CBO do not materialize.

What is potentially more egregious than the vast increases in mandatory spending created by this law are new slush funds created in the Treasury outside the control of Congress and the staunch oversight of this committee. Meanwhile, the unprecedented layers of Federal bureaucracy created by this law and the countless mandates on employers, insurance providers, doctors, and patients, have increased health insurance premiums that families pay at a time when long-term unemployment remains at historical highs, and family budgets are squeezed by higher gas and electric prices.

Certainly I hope you recognize the peril and the unsustainability of this constant rise in mandatory spending, particularly where Medicare is concerned. We have been told that Obamacare will help alleviate the looming shortfall in Medicare through various new programs, boards, payment schemes, that will bring savings to the program. However, the CBO recently reported that demonstration projects aimed at achieving savings in the health care sphere have historically failed to do so, and that the payment reductions envisioned in this law likely will not be put in place.

Yet even if savings are achieved through these various schemes, these funds have already been earmarked to pay for new entitlements created by Obamacare, not to save Medicare. You cannot count that money twice.

These are not trivial issues. If mandatory spending is not brought under control, these programs will fold, and the vital needs they address will go unmet.

I think it is critical that we stop living in a fantasy land where the money never runs out.

This past calendar year, this committee passed two Fiscal Years of appropriations. That has never happened before, to my knowledge. What has not happened since World War II is we cut discretionary spending two years in a row. That is a real rarity.

The discretionary spending is not the problem. If we zeroed out every penny we appropriate of the discretionary budget, we would still be in the red every year because of the mandatory entitlement

spending. And yet we blindly go ahead without tackling the problem, and it is a growing problem. And unless we deal with it, I am afraid for our future.

I wonder what you think about it.

Secretary SEBELIUS. Well, Mr. Chairman, I think that in the two years since the Affordable Care Act has been passed, we have some good news to report. I share your concerns about the deficit looming for our children and grandchildren, and also about the survival of entitlement programs. And as you know, there are two very different approaches. One approach is to address the entitlement programs. This approach would fix the dramatic rise in underlying health care costs, which not only helps the Federal government's budget, but it also helps private payers. And, the other is to blow up the programs as we know them, and shift the costs on to beneficiaries. We have chosen to go down the earlier described path.

And what I can tell you is that the Budget figures for the Affordable Care Act, which is fully paid for, does not add to the deficit, and will save $100 billion in the first decade, and a trillion dollars in the second decade.

We are seeing good news on the Medicare front, as predicted. The spending of Medicare prior to the passage of the Affordable Care Act was rising at the rate of about 8 percent, just under 8 percent a year. We are now seeing the growth rate for the last two years slow to just over 6 percent. That is good news, and that is not only money going back to the Medicare Trust Fund, but it is money in the pockets of beneficiaries. The program is stronger than ever. This budget adds an additional couple of years to the Trust Fund life.

But we certainly support the initiative of working with Congress to preserve the important promises made to beneficiaries about 45 years ago; that we will provide security for seniors and the most disabled citizens in this country as they move forward. We will take advantage of what we think are incredible opportunities to change the trajectory of the overall health spending in this country because it is not just the public programs going broke, but it is the health care system that is bankrupting business and private payers alike.

Mr. ROGERS. Thank you, Mr. Chairman.

Mr. REHBERG. I am going to try to get back to a little bit of regular questioning. Ms. DeLauro.

AFFORDABLE CARE ACT IMPLEMENTATION

Ms. DELAURO. Thank you, Mr. Chairman.

Madam Secretary, as you started to outline, there are a number of important protections for patients and consumers in the Affordable Care Act, and those have already taken effect. And I know your department has been working with the States to implement that.

I am going to ask you about the status of the implementation efforts and the main provisions that are now in place and working, and what results have been achieved so far.

I will ask the follow-up now that there have been repeated attempts in this House to cut off funding for the Affordable Care Act implementation. And if such a funding prohibition were to become

law, what would happen to the department's ability to implement and enforce rules, such as the ban on excluding children's pre-existing health conditions from insurance coverage?

Now, I will say that, but I also wanted to commend to my colleagues something called The Affordable Care Act is Already a Success. I know the chairman asked about women and children. I think one ought to take a look at the $14 million in school-based health centers that increased the number of children served by about 50 percent, 350 new community health care services, 2.5 million young adults who gained health care, who got insurance coverage. And millions of women who are taking advantage of the no-cost-sharing preventive health services in 2011 will have access to women's preventive health services, and including those that would be effective in August.

There is a wonderful chart, which I would include in the record, which shows the 54 million Americans estimated to be receiving expanded preventive services coverage under the Affordable Care Act.

[The information follows:]

ASPE
ISSUE BRIEF

FIFTY-FOUR MILLION ADDITIONAL AMERICANS ARE RECEIVING PREVENTIVE SERVICES COVERAGE WITHOUT COST-SHARING UNDER THE AFFORDABLE CARE ACT

By:
Benjamin D. Sommers and Lee Wilson, ASPE

The Affordable Care Act requires many insurance plans (so-called 'non-grandfathered' plans) to provide coverage for and eliminate cost-sharing on certain recommended preventive health services, for policies renewing on or after September 23, 2010.[1] Based primarily on guidelines from the U.S. Preventive Services Task Force, this includes services such as colonoscopy screening for colon cancer, Pap smears and mammograms for women, well-child visits, flu shots for all children and adults, and many more.[2]

While some plans already covered these services, millions of Americans were previously in health plans that did not. According to the Kaiser Family Foundation's Employer Health Benefits Survey in 2011, 31% of all workers were covered by plans that expanded their list of covered preventive services due to the Affordable Care Act.[3] The most recent data from the Census Bureau show that 173 million Americans ages 0 to 64 currently have private coverage.[4] Putting these facts together, we estimate that approximately 54 million Americans received expanded coverage of at least some preventive services due to the Affordable Care Act in 2011.[5]

Using national survey data on children and adults with private insurance, we next estimated how those 54 million people are distributed across states, and across age, race, and ethnic groups. We examined the following age/gender groups, and provide here a sample of the services they are now eligible for without any cost-sharing. Note that this is not an exhaustive list of covered services and is only meant to highlight several examples.

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[1] *Preventive Regulations*. U.S. Departments of Treasury; Labor; and Health and Human Services.
[2] *Recommended Preventive Services*. U.S. Department of Health and Human Services, 2011. Accessed at: (http://www.healthcare.gov/law/resources/regulations/prevention/recommendations.html)
[3] Kaiser Family Foundation – Health Research and Education Trust. Employer Health Benefits: 2011 Summary of Findings. Exhibit 13.6 shows that 31% of workers were in plans "where the services considered preventive changed because of the ACA." The same analysis shows that 23% of works were in plans "where cost sharing changed for preventive services because of the ACA." We made the conservative assumption that these two groups overlapped completely, meaning that 31% experienced expanded coverage and/or reduced cost-sharing, though in fact if some people in the second group were not in the first, the overall percentage affected could have been even higher than 31% and as high as 54% (31% + 23%).
[4] DeNavas-Walt C, Proctor BD, Smith JC. Census Bureau, Current Population Reports, P60-239, Income, Poverty, and Health Insurance Coverage in the United States: 2010, Government Printing Office, Washington, DC, 2011.
[5] We included people with non-group plans in this calculation, since non-group coverage tends to be less generous than employer-provided insurance, suggesting that at least 31% of people in the non-group market likely experienced expanded coverage for preventive services due to this provision.

- **Children (0-17):** Coverage includes regular pediatrician visits, vision and hearing screening, developmental assessments, immunizations, and screening and counseling to address obesity and help children maintain a healthy weight.

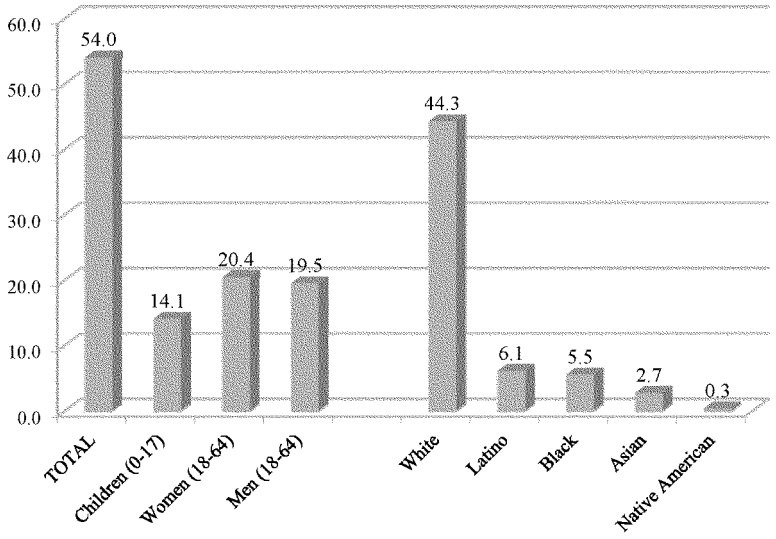
- **Women (18-64):** Coverage includes cancer screening such as pap smears for those ages 21 to 64, mammograms for those ages 50 to 64, and colonoscopy for those 50 to 64; recommended immunizations such as HPV vaccination for women ages 19 to 26, flu shots for all adults, and meningococcal and pneumococcal vaccinations for high-risk adults; healthy diet counseling and obesity screening; cholesterol and blood pressure screening; screening for sexually-transmitted infections and HIV; depression screening; and tobacco-use counseling. Starting in August 2012, additional preventive services specific to women, such as screening for gestational diabetes and contraception, will be covered by new health plans with no cost sharing.

- **Men (18-64):** Coverage includes recommended immunizations such as flu shots for all adults and meningococcal and pneumococcal vaccinations for high-risk adults; cancer screening including colonoscopy for adults 50 to 64; healthy diet counseling and obesity screening; cholesterol and blood pressure screening; screening for HIV; depression screening; and tobacco-use counseling.

Figure 1 presents national totals, including breakdowns by age, gender, race and ethnicity. Table 1 presents totals by state.[6]

[6] Data come from the Census Bureau's Current Population Survey, for the years 2009-2011. We use three pooled years to allow for state-level estimates. We analyzed the proportion of all non-elderly individuals (0-64 years old) with private insurance in each category and state listed in Figure 1 and Table 1, and scaled the survey-weighted percentages to total 54 million individuals in aggregate, to match the projected number of people affected by this policy. Note that this overall approach is only a rough approximation and does not reflect any potential uneven distribution of individuals by age, race/ethnicity, or state of residence in private plans affected by the preventive coverage provisions of the Affordable Care Act.

FIGURE 1: Number of Americans Estimated to be Receiving Expanded Preventive Services Coverage Under the Affordable Care Act (in Millions)[7]



[7] The Census Bureau records race and ethnicity separately, which means that totals combining racial and ethnic groups sum to more than 100%.

TABLE 1: Number of Americans Estimated to be Receiving Expanded Preventive Services Coverage Under the Affordable Care Act, by State

State	Total	Children	Women	Men
Alabama	819,000	205,000	319,000	294,000
Alaska	121,000	33,000	44,000	44,000
Arizona	1,056,000	282,000	389,000	385,000
Arkansas	439,000	110,000	170,000	159,000
California	6,181,000	1,638,000	2,286,000	2,257,000
Colorado	973,000	259,000	362,000	352,000
Connecticut	710,000	188,000	270,000	252,000
Delaware	163,000	43,000	61,000	58,000
District of Columbia	107,000	17,000	47,000	42,000
Florida	2,841,000	710,000	1,104,000	1,027,000
Georgia	1,713,000	465,000	654,000	593,000
Hawaii	240,000	59,000	90,000	91,000
Idaho	283,000	86,000	100,000	97,000
Illiuois	2,390,000	605,000	898,000	887,000
Indiana	1,160,000	314,000	421,000	425,000
Iowa	611,000	158,000	225,000	228,000
Kansas	529,000	141,000	198,000	191,000
Kentucky	732,000	184,000	274,000	273,000
Louisiana	719,000	193,000	275,000	251,000
Maine	226,000	53,000	91,000	82,000
Marvland	1,153,000	297,000	448,000	408,000
Massachusetts	1,324,000	327,000	517,000	480,000
Michigan	1,849,000	498,000	692,000	658,000
Minnesota	1,056,000	281,000	392,000	383,000
Mississippi	430,000	111,000	167,000	152,000
Missouri	1,102,000	292,000	408,000	401,000
Montana	166,000	41,000	62,000	63,000
Nebraska	359,000	96,000	134,000	129,000
Nevada	477,000	133,000	171,000	173,000
New Hampshire	279,000	70,000	107,000	102,000
New Jersey	1,694,000	449,000	628,000	617,000
New Mexico	285,000	75,000	111,000	100,000
New York	3,342,000	824,000	1,322,000	1,196,000
North Carolina	1,564,000	403,000	600,000	561,000
North Dakota	130,000	33,000	49,000	48,000
Ohio	2,138,000	559,000	797,000	782,000
Oklahoma	616,000	160,000	236,000	220,000
Oregon	692,000	171,000	273,000	248,000
Pennsylvania	2,363,000	580,000	915,000	869,000
Rhode Island	195,000	46,000	76,000	72,000
South Carolina	755,000	201,000	296,000	258,000
South Dakota	151,000	41,000	56,000	54,000
Tennessee	1,044,000	263,000	401,000	380,000
Texas	3,836,000	1,049,000	1,421,000	1,366,000
Utah	605,000	207,000	199,000	198,000
Vermont	115,000	24,000	47,000	44,000
Virginia	1,519,000	410,000	576,000	533,000
Washington	1,239,000	293,000	483,000	463,000
West Virginia	300,000	75,000	113,000	112,000
Wisconsin	1,111,000	295,000	413,000	403,000
Wyoming	102,000	28,000	36,000	38,000
TOTAL	54,004,000	14,075,000	20,424,000	19,499,000

Ms. DELAURO. And you will see, quite frankly, that children and women are taking advantage of the new efforts that have gone into effect.

Madam Secretary, let me ask you to comment on the status of the implementation, the main provisions in place, the results so far, and then what would happen if the funding is gone as some of our colleagues would like to see enacted.

Secretary SEBELIUS. Well, Ms. DeLauro, I think you have outlined some of the changes that have taken place, but let me put it in a couple of buckets.

There are some fundamental changes that have started to take place in the insurance market. Companies can no longer deny children with preexisting health conditions the ability to be in the insurance market. That is great news for parents. Children and young adults can stay on their parents' plan up to age 26, and we know that about 2 and a half million of those young adults have taken advantage of that. Companies can no longer dump somebody out of the market because of a technical mistake on their application; the so-called rescissions are now illegal. Insurance companies will no longer be able to put a lifetime limit on benefits, and while this affects a very small number of people, this situation is a life and death situation when these limits are reached in the midst of a health care treatment.

Preventive services and new health plans are now available without co-pays or co-insurance, and that not only is true for the private market, but it is true for Medicare. And we know that millions of people are taking advantage of getting the preventive colon cancer screenings, mammograms and preventive checkups that they need.

Seniors are now seeing a 50 percent discount in their brand name prescription drugs when they hit the so-called donut hole, and that has impacted millions of seniors this year with real money in their pockets. We have new rates that have been negotiated for Medicare advantage plans thanks to the tools that we have gotten. So, more people are enrolling, but the rates are down, which is, again, good news for seniors.

In addition, new community health center access sites are being developed. And, that is in a little under two years.

AFFORDABLE CARE ACT FUNDING PROHIBITION

Ms. DELAURO. If the funding prohibition goes into law, what happens, Madam Secretary?

Secretary SEBELIUS. Well, I think it is safe to say that a number of those programs either would vanish or be seriously threatened. And I am not quite sure what happens with our ability to operate Medicare programs because so many of the changes in Medicare are ones that were directed through the Affordable Care Act. So, we have staffers and funding that are available through that Act.

Also, I would tell you that the toughest anti-fraud measures ever passed in this Congress in history are part of the Affordable Care Act. And as I said, $4 billion was returned last year, and another $375 million was identified. We have also built predictive modeling. That is a 7 to 1 return on dollars in, dollars out. Again, I think all of that is threatened and jeopardized if the funding goes away.

Ms. DELAURO. I compliment you on the anti-fraud measures. Thank you.

Mr. REHBERG. Mr. Alexander.

FRAUD AND ABUSE

Mr. ALEXANDER. Thank you, Mr. Chairman.

Madam Secretary, you were just talking about the fraud and abuse, and we have made some pretty good strides over the years, as you indicated. But you mentioned the relatively high rate of return on the investments for fraud and abuse dollars. But the question is, how much of that money that we are providing for fraud and abuse goes to the so-called pay and chase, and how much is actually dedicated toward prevention, because we know that there could be a lot of fraud and abuse cases stopped if we prevented it to begin with.

Secretary SEBELIUS. You are absolutely right, Congressman. And I think one of the great opportunities we have had with some of the new resources and some of the new tools given to us as part of the Affordable Care Act is to build a new data system, bringing all of the Medicare bills into one place so that they can be viewed across the Department.

But more importantly is our ability to build a predictive modeling data analysis system so we can do what the private sector has done for years, which is to spot errant billing. The way we identified the doctor in Texas who allegedly is the ring leader for this massive home health service fraud was using the kind of data analytics that just did not exist a couple of years ago.

So, those new tools are all about prevention. But, we still are doing some of the other techniques like paying and chasing and trying to spot errant bills before they go out the door. But I think that our efforts can only get better over time.

Mr. ALEXANDER. And you also stated that the budget makes Medicaid more flexible, and that by 2013 it would be critical in working with States to set up the infrastructure for the exchanges in the health care plan. In Louisiana, that exchange will be a Federal exchange set up by CMS, which is supposed to be up and running in about 22 months from now. Yet to date, we are hearing from the State Medicaid officials that they have not yet had guidance from CMS on the coordination activities that will be required between the Federal exchanges to set that program up.

So, can you tell me what plans HHS or CMS has to do this, because our State Medicaid programs are concerned, extremely concerned, about it. And can you also give us more information on the flexibility mentioned in the testimony?

Secretary SEBELIUS. I would be glad to, Congressman. We are working very closely with States, and, in fact, had a number of meetings just 10 days ago when all the governors and their staff were in town.

We have put out guidance in terms of the framework for both the exchanges and the Medicaid enhancement and enrollment. States will be principally responsible for the Medicaid piece of the puzzle, whether or not it is in a Federally run exchange, a State-run exchange, or a partnership program, which are the three models that States are looking at. And we are trying to anticipate questions,

issues, and have a lot of hands-on work going on with States around the country, including your home State of Louisiana.

I can tell you that the Budget request that is before this Committee that the Chairman referenced earlier, which includes some enhanced funding for administration at CMS, will be used for one-time costs to establish the framework around the Federally-based exchanges. That is a critical part of this puzzle to make sure that we are up and running for the States that choose not to operate their own exchanges, or the States that want to be in a partnership effort.

But the goal will be that when a consumer wants to take advantage of an exchange program or health insurance, that they will be able to come through one portal and determine whether they qualify for an exchange with the tax credit, or whether they qualify for Medicaid and be pretty seamlessly enrolled.

Mr. ALEXANDER. Thank you.

Mr. REHBERG. Ms. Roybal-Allard.

PREVENTION PUBLIC HEALTH FUND

Ms. ROYBAL-ALLARD. Welcome, Madam Secretary.

I co-chair the Congressional Study Group on Public Health, and in that role I have been closely following the public health portions of the HHS budget for several years. And while I commend you for your efforts to address difficult financial decisions, I am concerned that CDC and SAMHSA budgets are being cut and back filled with monies from the Prevention and Public Health Fund, which was intended to get a step ahead of the grim reality that we spend approximately 70 to 75 percent of our health care dollars on treating chronic, preventable diseases.

I know that you are a strong supporter of CDC and SAMHSA, and that you champion the PPH Fund in the Affordable Care Act. So, I would like to know the rationale for targeting the two public health agencies for the department's largest budget cuts, and how you anticipate that they will be able to continue with their mission.

My concern is heightened also by the fact that $5 billion was taken out of the Prevention Fund earlier this year to pay for the District of Columbia fix. And will any of this money be coming out of CDC and SAMHSA core programs, which our budget proposes back filling with the PPH Fund?

Secretary SEBELIUS. Well, Congresswoman, I assure you that your concerns about a strong public health infrastructure are certainly shared within our Department and within the Administration. The President also shares those concerns.

And the use of some of the Prevention and Public Health Fund dollars for some of the CDC mission is one that we certainly would not do in a better budget time, but given the budget constraints, we are both not only enhancing CDC's budget with some of the funds, but also making sure that the funds focus on some new initiatives going forward.

SAMHSA has made some recommendations in the Budget, which we are presenting to you again, to more efficiently, I think, use some of their funding. It is programmatic restructuring at the State level that they feel will not diminish the public health infrastructure, but rather will allow these dollars to be used in a more

flexible way by their State partners, so that I think in both cases we can make a strong argument that the public infrastructure is being protected.

Would it be preferable that 100 percent of these budgets were funded, plus a full use of the Prevention Fund? That would be the goal, but I think given the restraint on spending and our interest in making sure we contribute to the overall budget picture, we feel that these recommendations are probably the best way to go about that.

SECTION 317 IMMUNIZATIONS

Ms. ROYBAL-ALLARD. Well, one of the concerns that I have is that given the fragility of the support for the Prevention Fund in today's political climate, that CDC and SAMHSA are made vulnerable in their ability to continue to carry out their core functions if this fund is eliminated or used for another pay for.

Another concern that I have about the proposed reduction is in the 317 Immunization Program, which, as you know, has been a huge success in providing the infrastructure for the Vaccines for Children Program. Vaccination programs have proven to be some of the most cost-effective approaches to preventing disease and reducing health care costs, and the Children's Vaccine Programs are estimated to be a 10 to 1 savings a paycheck.

A Fiscal Year '11 report to this committee from CDC estimated that the 317 Program was underfunded by hundreds of millions of dollars. If this is still the case, how do you anticipate addressing the impact of cutting this program by $58 million or close to 10 percent?

Secretary SEBELIUS. Well, again, Congresswoman, I think that it is the view of Dr. Frieden and the experts who work with the Children's Vaccine Program that the resources that we have requested will allow us to continue to run this very successful program in partnership with States around the country. We are continuing to do outreach to maximize these resources, and are hopeful that this cut will not jeopardize the important public health initiative that the Children's Vaccine Program represents.

Mr. REHBERG. And you can always provide additional information for the record, Secretary Sebelius.

Ms. Lummis.

MEDICARE

Ms. LUMMIS. Thank you, Mr. Chairman.

Madam Secretary, as you know, we spend almost twice as much on Medicare in this country as we take in. And Medicare cannot go on like that. It is going to be broke soon. And for the fifth consecutive year, the Medicare trustees have issued a Medicare funding warning, which means that general revenues do account for more than 45 percent of Medicare funding. So, under this trigger, the President is legally required to submit a legislative proposal to Congress to address Medicare's solvency within 15 days of a budget submission.

Now, President Obama's predecessor complied with that law and submitted legislation in 2008. But President Obama has never complied. So, was there ever a conversation between you and the

President about complying with the law? And what led to your decision not to comply with the law?

Secretary SEBELIUS. Congresswoman, the President has submitted a Budget which very much complies with the law, and it is a legislative proposal. And he feels that that is sufficient to comply with the trigger.

I am one of the Medicare trustees. I know that trigger exists, and that is why he has a Budget which reduces the overall deficit and leaves Medicare solvent in the future.

Ms. LUMMIS. Tell me specifically how his budget complies with that specific law.

Secretary SEBELIUS. The budget——

Ms. LUMMIS. Yes.

Secretary SEBELIUS [continuing]. Taken as a whole reduces the deficit and fully funds Medicare. And it does comply with the Medicare figure.

Ms. LUMMIS. It reduces the budget by the 45 percent, the full 45 percent every year that is being augmented by the general fund?

Secretary SEBELIUS. I think if you look at the 10-year Budget that the President has submitted to Congress this year——

Ms. LUMMIS. Does it do it every year?

Secretary SEBELIUS. Last year, the year before, it does do it, Congresswoman.

Ms. LUMMIS. Year by year, is it back end loaded?

Secretary SEBELIUS. I think it is complying with the law. That is what we have interpreted, and that is what was submitted to this committee.

INDEPENDENT PAYMENT ADVISORY BOARD

Ms. LUMMIS. I have a question about the Independent Payment Advisory Board in that regard. The President's budget makes reference to a value based benefit design. What does that mean? What is a value based benefit design?

Secretary SEBELIUS. Well, I think if you talk to a lot of the best health systems in the country, they will tell you that paying for volume, such as the number of things done to a person, the number of days in the hospital, the number of tests run, is probably not only driving up costs, but is counterproductive because great health care systems, which keep people healthier in the first place, are financially penalized by that type of activity. What is more effective is to look at strategies which actually keep people healthier in the first place, reduce the acute illnesses, try and eliminate preventable harm to patients, everything from hospital-based infections to preventable readmissions. And that is a value based proposal—there should be a funding mechanism that does not penalize systems and providers for keeping people healthy, but rather actually rewards them.

Ms. LUMMIS. I am told there will not be a rulemaking on this, so it is going to be up to the board to define these terms? Is that correct?

Secretary SEBELIUS. I do not really know what it is that you are talking about. The Board——

Ms. LUMMIS. The board will define value based——

Secretary SEBELIUS. The Independent Payment Advisory Board will make recommendations to Congress. If a certain trigger is met by Medicare, if Medicare spending exceeds a projected level, they will be making recommendations to Congress about ways to reduce Medicare spending. So, I am not——

Ms. LUMMIS. So, the Independent Payment Advisory Board will define value based benefits.

Secretary SEBELIUS. I apologize. I can go back to the statute, see where it is in the statute, try and figure out who defines it. But I do not really know in what context it is that you are putting that.

The Independent Payment Advisory Board, I can tell you, cannot make recommendations that ration care, raise beneficiary premiums or cost sharing, reduce benefits, or change eligibility. Can they make recommendations about better ways to deliver health care? I hope so.

Ms. LUMMIS. And my concern here is that this board will set Medicare policy unless a super majority of Congress stops them. And so, if the board has things called like value based benefits, but nobody knows what that means because there are no rules, and the board is telling people what that means, how are we supposed to know?

Secretary SEBELIUS. Well, again, Congresswoman, the Board does not have any authority beyond making recommendations to Congress. A simple majority in Congress can either accept their recommendations or substitute recommendations. So, it is not a super majority, it is a simple majority, in both the House and the Senate, is the way the rules are written.

If Congress fails to act, if Congress fails to keep the costs of Medicare below the trigger, and then fails to accept the recommendations, then I am directed to move on the recommendations. But a simple majority of Congress can act, and the IPAB, as I say, is prohibited, by law, from rationing care, raising premiums, reducing benefits, or changing eligibility.

Mr. REHBERG. Mr. Dicks.

HEALTH CENTERS

Mr. DICKS. One of the most useful things about the health care reform, as far as I am concerned, is the additional funding to greatly expand the network of health centers, building on the base of support provided in the Labor, HHS appropriations bill.

As the Affordable Care Act increases the number of people who have health insurance, health centers can help provide a place to use that coverage in areas that are otherwise short of good primary care. The goal is to help people stay healthy, as you have mentioned, and to get people detected and treated before they become seriously ill and expensive. That improves health and, in the end, it also helps lower costs.

Can you tell us how the department has been making use of the combination of funding provided in the bill and the Affordable Care Act to expand health care sites and services?

Secretary SEBELIUS. Yes, I can, Congressman.

First of all, I want to recognize that I think community health centers are a topic where there has been a lot of bipartisan support and a lot of leadership from this Committee over the years, and

certainly have been an enormously important infrastructure for lower cost delivery of primary care and preventive care.

We are in the process of not only using the resources provided by the Affordable Care Act, but also by the Recovery Act, to expand access points in sites, to match newly trained health care providers with the most underserved areas. And with the funding of this Budget, we look forward to the opportunity to have about 21 million Americans throughout this country in the most underserved areas have access to this high quality, lower cost preventive care.

Mr. DICKS. You know, in my district we have a number of these health care clinics, and I think they provide a tremendous service to the people in our area. And I have often thought that with all the controversy, maybe we should have just expanded this program to take care of everybody who needed help. It might have been less controversial. But, again, I just urge you to keep moving forward on that particular program.

HEALTH CARE FRAUD

You mentioned the health care fraud. Now, we had a problem last year. We did not get the extra money necessary to expand the program. And as you said, we save $7 for every $1 invested, so it seems to me this is like the IRS agents that were going to be cut last year, and we finally got that straightened out.

I mean, I think we should, especially since you have just had this great success, we should keep the pressure on and get the right people involved, and try to shut down a lot of these rackets that are going on around the country.

Secretary SEBELIUS. Well, Congressman, I share that view. I think unfortunately our Inspector General's Office was hopeful that the full funding was forthcoming in the fiscal year 2012 Budget so that it could have expanded some additional resources. They are going to hold tight now, but we would urge the Committee to look at the additional $270 million that would strengthen the efforts, and I think is, again, a real win-win situation.

We are building this very aggressive partnership with not only law enforcement and our Inspector General's Office, but also with U.S. attorneys and inspectors on the ground. And we now have strike forces in nine cities. We would like to expand that further. We think that the efforts are really beginning to pay off, and think that anything that this Committee can do to make sure that those investments are fully funded would be very much, not only appreciated, but I think appreciated by the taxpayers.

EXCHANGES

Mr. DICKS. One of the increases you are seeking at CMS is for expenses involved in setting up the new insurance exchanges that are scheduled to begin operation in 2014. What has to happen in order for this to move forward?

Secretary SEBELIUS. Well, Congressman, the original Affordable Care Act passed and signed into law in March two years ago appropriated $1 billion for implementation of health reform. At the time, the Congressional Budget Office estimated that it would cost about a billion dollars a year in implementation costs until it was fully realized.

I think the good news is that we have spent under that estimated amount. We are now two years in, and have spent about $475 million. But the remainder of that billion dollars we anticipate being gone by the end of fiscal year 2012. We have requested in this Budget a new——

Mr. DICKS. Does the money expire? Is that what you are saying?

Secretary SEBELIUS. No. It is being expended and drawn down.

Mr. DICKS. Okay. But it will be gone.

Secretary SEBELIUS. That is correct, so that this fiscal year 2013 request is for a billion dollars, $200 million of which will be spent on Medicare and Medicaid, and about $800 million will help build the primary infrastructure, a lot of one-time costs for the Federally-run exchanges.

Mr. DICKS. Thank you, Mr. Chairman.

Mr. REHBERG. Thank you. Ms. Granger.

DRUG SHORTAGES

Ms. GRANGER. I just want for a comment to second what Mr. Dicks said about community health centers. The ones I have been involved in have done excellent work.

And my question is, as you know, there have been shortages of critical drugs, including drugs to treat pediatric cancers over the past years. I do not know of anything that really is more serious than that. But my understanding is that there are several potential sources of this problem: the closing of factories that produce the pharmaceuticals, low payment rates for these drugs, and a shortage of the raw materials that produce these pharmaceuticals.

I know the FDA has taken action to require companies to provide FDA notification of upcoming shortages, but what are you doing to solve this problem of shortages of really critical pharmaceuticals?

Secretary SEBELIUS. Well, Congresswoman, I think this is a very high priority within our Department, and we are really looking at all the tools that we have.

Currently we do not have a mandatory reporting, and we are trying to work with Congress to see if that can be put into place because what we know is that since the President's executive order was signed in October, about 100 additional shortages have been eliminated by companies ramping up their voluntary reporting. So, that is a big step.

We also are expediting at the FDA re-inspections, looking around, the importation possibilities as drug shortages become available. At least as far as we can determine, and we would be happy to share this with you, the pricing issue is really not as much of an issue as some of the others because the prices are negotiated well in advance by the purchasing contracts. And so, it is not the end user that is negotiating the price; it is really kind of predetermined at the hospital level.

But certainly capacity is being expanded with the manufacturers, and I think that is another very critical piece of the puzzle. And we are committed to expediting those inspections as rapidly as possible.

But it is an issue that we are trying to analyze what levers we have and how fast we can move. But I think the mandatory reporting that is currently before Congress would be a big step.

Ms. GRANGER. Good. Thank you.

GRADUATE MEDICAL EDUCATION PROGRAM

The second question, at the budget hearing last year, we discussed your decision to eliminate the Children's Hospitals Graduate Medical Education Program funding. And at that hearing, you said that this was one of the toughest budget cuts that had to be made in this request, and in better budget times, you said, you would not have recommended this. I was pleased that your budget request for this year did not zero out this funding, but it still proposed a severe cut in the program.

When I look at the funding for HHS that was included in the health care law, I was surprised that you do not think that you are in better budget times. Your budget request for 2013 includes funding for implementation of the health care law, including the $1 billion increase for CMS that you cited in your testimony.

So, could you please help me understand how new programs in the health reform law were supported in your budget, but the Children's Hospital Graduate Medical Education Program, a program you acknowledged as having had substantial success, was subject to a severe cut?

Secretary SEBELIUS. Certainly, Congresswoman.

The Budget request that we have pending before this Committee is our estimation for what it will take to cover the direct costs for the pediatric residents that are in training. What it does not cover is the indirect costs of those residents, so we are hopeful that this will preserve the number of teaching slots.

We also are looking at the number of other programs which also support training in pediatrics, including the National Health Service Corps. We have a new teaching health center graduate education program. Many of these are funded through the Affordable Care Act, as you just have referenced, so we are focusing some of those resources on this very critical area. The primary care training and enhancement, we have got scholarships for disadvantaged students, including those training to be pediatricians, maternal health and child training programs, a new pediatric loan repayment.

So, using some of the Affordable Care Act funding for the workforce initiatives, we are trying to redirect that funding as much as possible to focus on primary care, and particularly on some of this pediatric training. So, we are looking at the range of issues. But the children's health graduate medical education payments are designed to support the direct costs of those pediatric residents.

Ms. GRANGER. Thank you.

Mr. REHBERG. Mr. Jackson.

Mr. JACKSON. Thank you, Mr. Chairman, for yielding me the time, and let me welcome Secretary Sebelius back to our committee. Let me also——

Secretary SEBELIUS. It is not your birthday this year. What is the deal with that? Where are the cupcakes? I mean, you know——

Mr. JACKSON. Thank you for reminding me. [Laughter.]

Secretary SEBELIUS. Just to put you all on notice, you know.

Mr. JACKSON. We actually did talk about that. [Laughter.]

Mr. JACKSON. I trust, Mr. Chairman, that did not come out of my time. [Laughter.]

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Mr. JACKSON. Let me also apologize in perfect candor for the position that we have put the Secretary of Health and Human Services under because, from my perspective, this Congress' inability, Madam Secretary, to pass a jobs bill and recognize a real need for the American people, that we should be putting Americans to work. If there were more Americans working, we would be paying more money into the Treasury. And many of the programs for which you have had to make difficult cuts, we would be in a position to not look at zeroing them out.

Towards that end, in 2011, the Low Income Home Energy Assistance Program served about 460,000 households in Illinois, which 83,955 recipients were in the 2nd congressional district. In the State, 50 percent of the funding was allocated to families earning below 75 percent of the Federal poverty level, and 24 percent was allocated to recipients between 75 and 100 percent poverty. Thirty percent of the recipients are elderly, 33 percent disabled. Twenty-two percent are under the age of 5. And these services are vital for the well-being of many of my constituents.

Madam Secretary, the Administration for Children and Families Budget states that, "Funding is prioritized for programs protecting society's most vulnerable." Clearly, the LIHEAP Program serves the most vulnerable among us, so why does the Administration's budget propose such a significant decrease in the LIHEAP Program? And would you also comment on the expected impact of the Administration's proposed 33 percent decrease from Fiscal Year '11 for LIHEAP and what its impact will be on low income recipients?

Secretary SEBELIUS. Well, Congressman, this is a very tough budget cut. It is about $450 million above the 2012 Budget, but we understand that it still is seriously under the budget from two years ago where there was a substantial increase in LIHEAP, and we have not been able to sustain that increase.

There is no doubt that the cuts fall on the low income families in a more difficult way, and certainly there is nothing more important than heating and cooling when you are talking about people's ability to stay in their homes.

So, I think that this will have an impact on folks. We are trying to look at how much we can allocate at the front end. And, as you know, we hold some funds in reserve to make sure that as temperatures change over the course of a season, and States have different needs for this funding, we can allocate it to not leave people in dire circumstances. But it is a very difficult cut.

HEALTH CAREERS OPPORTUNITY PROGRAM

Mr. JACKSON. Madam Secretary, I know you have a difficult task in selecting how to spread proposed funding reductions across the budget proposal. However, I am disappointed in the Fiscal Year 2013 recommendation to eliminate the Health Careers Opportunity Program, or HCOP. The budget justification explains this reduction by stating the funding allocations for training are being focused on programs that have a direct link to a training program for primary

health care professionals. Unfortunately, this does not take into account the importance of preparing individuals from disadvantaged backgrounds or medically underserved communities for a health career.

Study after study demonstrates that individuals from medically underserved communities are far more likely to return to their communities as a health professional. If no effort is made to provide opportunities for disadvantaged students from medically underserved communities, like through HCOP, the training funds are more likely to be distributed among those who will end up serving in non-medically underserved communities. I do not see how this helps reduce health disparities, and it does not, from my perspective, narrow the health status gap.

Should we not be dedicating our limited funding to a demographic that is in greatest of need?

Secretary SEBELIUS. Well, Congressman, I think that, again, we are trying to do that. There are definitely lines of funding specifically aimed at minority and underserved communities. There is almost a $50 million scholarship programs for disadvantaged students who want to become health professionals. We have the National Health Service Corps, which, as you know, not only trains folks, but pays off loans for people who agree to serve in underserved areas, and they are doing that with a particular focus at this point to not only reaching into underserved communities to recruit those trainees, but also looking at returning veterans. We have a commitment to train and hire veterans returning who have qualified skill sets. And that program has tripled over the last three years. We have some primary care training and enhancement programs that are, again, looking at streams of funding for underserved communities and for students coming out of minority communities.

So, I would agree that that is a huge issue, and one that we are trying to pay careful attention to as we expand these programs.

Mr. REHBERG. For the record, you got an additional 30 seconds beyond the 20 we wasted.

Secretary SEBELIUS. And we still do not have cupcakes.

Mr. JACKSON. Forty-seven and 30 seconds. Thank you, Mr. Chairman.

Mr. REHBERG. Mr. Kingston.

HEALTHCARE PREMIUMS

Mr. KINGSTON. Madam Secretary, putting on your hat as a Medicare trustee, I am concerned, and I would think that the Trustees would be very concerned, with some of the rosy assumptions of the President's budget. Some would call them gimmicks. For example, under the category of deficit spending, he counts war savings, which according to the recent developments in Afghanistan even though the President says he has calmed it down because of the Koran burning, it does not look like the war is going to wind down exactly as planned. He also makes some great assumptions about tax increases and economic growth.

I do not know if you have seen those, but I would recommend as a trustee that you go back and review that because it would appear to me that his assumptions of deficit reduction are really irrespon-

sible, very political, but also to the trustees they would be considered irresponsible. So, I would recommend that to you.

Also, you had said that in response to the success of the health care bill that there is a high enrollment of seniors, children, and high-risk people. And I understand that. But reacting to free money and government money is not necessarily a sign of success. What I am more disturbed about is that the President claimed that Obamacare would bring down the costs premiums for the average middle class family to $2,500, and yet the Kaiser Foundation estimates that the total premiums have gone from $12,860 in 2008 to $15,073 per year. So, instead of decreasing the American middle class families' premiums by $2,500, Obamacare has, in fact, increased premiums by $2,213.

And the point being is when we say, well, this is wonderful, the kids are now,—and I do not know why we call people the age of 26-years-old kids, but now they are taking advantage of some good program and they get to stay on mom and dad's health care. There is nothing really remarkable about that. It is just, hey, free money, come and get it. And yet, when they look at their premiums, the middle class families are picking up the tabs.

So, as you may suspect from my comments, I have some philosophical disagreements with the Administration on this program. But I want to say that to you as a trustee because to me it scares me to think that the trustees are really counting on the Obama budget to give a realistic picture of the future of Medicare when we do know Medicare is going broke. And I would assume that the trustees would be concerned about that.

Secretary SEBELIUS. Mr. Kingston, I think the trustees are very concerned about the long-term solvency of Medicare, and are eager to implement the strategies that I told you are already beginning to show very promising impacts.

I would say in terms of your analysis of the private insurance market, you are absolutely correct. And it is even more glaring if you could look at what has happened in the decade before the passage——

Mr. KINGSTON. So, well, you would admit then that the President——

Secretary SEBELIUS. Mr. Kingston, could I just respond to the——

Mr. KINGSTON. Well, let me reclaim the time then. You would admit that the President's assumption on claims that premiums were going to be reduced $2,500 was wrong then, because that was what he was claiming the premium savings would be.

Secretary SEBELIUS. No one ever claimed that premiums would be reduced until there was a new insurance market, which does not exist yet.

Mr. KINGSTON. Okay.

Secretary SEBELIUS. So, you are absolutely right. You are looking at what has happened to the private insurance market, but it well pre-dates the passage of the Affordable Care Act. This market is on a death spiral where younger and healthier small business owners, and others, are leaving the market as health care costs spiral. Our plan includes a new insurance exchange run at the State level or the backup plan to be run at the Federal level, because the mar-

ket is broken. It is broken for small business owners. It is broken for individuals buying their own policies. They are paying the brunt of these skyrocketing costs.

And you are absolutely right, that has not changed yet because the new market is not in place until after 2014.

LOBBYING

Mr. KINGSTON. Well, when we hear some of the assumptions that are made—for example, the stimulus bill was supposed to bring down the unemployment to, I think, 6 and a half percent, and we are still lingering at around 9 percent. So, I get very concerned when I hear the government making these great promises.

Let me ask you this very specifically. The Prevention and Public Health Fund is about a billion dollar fund. And part of the resources by the Philadelphia Department of Public Health, which received a $10.4 million CDC grant, were used to lobby for a 2 cent per ounce tax on sugar sweetened beverages. And I was wondering, is that the purpose of that grant, to let a local government lobby for a higher tax increase?

Mr. REHBERG. I will ask you to answer very quickly because we are trying to make it all the way through all of our members, and you asked the question right at the end of your time. So, if you could answer very quickly.

Secretary SEBELIUS. Well, our long-term guidance, both within the Department and through OMB to grantees, has always prohibited lobbying either at the Federal level or lobbying at the State level.

The Congress added some additional language to our fiscal year 2012 Budget which is new, and for the first time talked about grantees not being able to either lobby administratively or to local units of government. We are updating our guidance and going to make sure that that happens.

Nothing prohibits any group from using their own funds to lobby, and nothing prohibits them from using Federal funds to provide technical assistance or education.

Mr. KINGSTON. Thank you.

Mr. REHBERG. Ms. Lee.

H.R. 2954

Ms. LEE. Thank you very much. Hello, Madam Secretary. Good to see you.

As you know, I introduced a comprehensive bill this Congress—it is H.R. 2954 on behalf of the Congressional Asian-Pacific American Caucus, the Hispanic Caucus, and the Black Caucus—to help address racial and ethnic disparities.

Now, this bill, it actually builds on the health care reform bill and includes additional tools necessary to address these challenges, especially around the area of data collection, culturally and linguistically appropriate health care and health information technology.

Now, many challenges, but one let me call your attention to. A study released last week showed that only 42 percent of eligible limited English proficient adults in California are expected to take part in the health benefit exchange. This means that some 100,000

Californians will miss out on health care expansion due to language barriers.

Now, I was pleased to see that you launched the action plan to end health disparities, but I am also concerned about some of the budget cuts that may undermine now all of your efforts, especially the 26 percent cut in the Office of Minority Health. And I understand the consolidation and coordination requirements. And certainly your agency has done a heck of a lot more than Secretary in any Administration in the past. But I am worried now that with the progress being made that this cut is going to really, really hurt.

And so, I would like to just get a sense of how you intend to provide targeted support to help reduce racial and ethnic disparities in health care, and also this whole issue with limited English individuals.

And then, secondly, nursing shortage. I was glad to see the $20 million for Advanced Education Nursing Program. There is a nursing shortage, yet about 40 percent of new graduates cannot find jobs. And so, there is this huge disconnect. And I have an 100-year-old aunt, and 87-year-old mother, a 91-year-old aunt, a sister who has multiple sclerosis. I am in hospitals and emergency rooms all the time. And every time I am there, there is a traveling nurse. And I am trying to get to the bottom of this.

And they are wonderful. They know what they are doing, but I go outside of the hospital, and then I am faced with my constituents who cannot get a job as nurses, even though they have graduated and have the credentials and experience.

So, I am trying to get to the bottom of this and try to see what we can do about making sure that nurses, especially minority nurses, get these jobs because they are just not getting them.

Secretary SEBELIUS. Well, let me try to address the nursing issue first because it is certainly one that we share. And what we know is that without a sustained production of new nurses in the workforce, we are going to be in terrible trouble. So, we are trying to use the resources directed to us to expand the pipeline, and expand the capacity, and continue to train nurses.

Having said that, we also know that there is not necessarily an accurate match between where the nurses are located and where the shortages are. Our Health Resources Services Administration is trying to do updated analysis of that pipeline, making sure that we are trying to get people to the spots where they have the training, locate centers where they can be trained. The expansion of the health center and the expansion of nurse run health centers is a part of that strategy. But we would love to continue to work with you. I know it is a huge issue for you.

I also think that, Congresswoman, we do have for the first time plans that are coming into place not only around the closing the gap on health disparities with very clear measurements and a timeline, thanks to a lot of the work of your leadership in the Congress. But in terms of the outreach to people who might be in the most underserved communities about the opportunity to enroll in health plans, that is certainly part of our outreach effort as we go forward.

In your State of California where they are likely to have a State-run center, we are working closely with the State to look at their

resources to make sure we reach in, and the Federally-run centers will do the same thing.

But getting people the information, particularly in the most underserved communities, about how they can take advantage of the benefits and the new health insurance opportunities is one of the big challenges.

Ms. LEE. Thank you. Mr. Chairman, I would like to submit the rest of my questions for the record.

Ms. LEE. And then, Madam Secretary, I would like to follow up with you with regard to the tri caucus disparities bill and talk about some of these policy and programmatic initiatives that we may be able to work on together.

Secretary SEBELIUS. Great. Thank you.

Ms. LEE. Thank you.

Mr. REHBERG. Mr. Flake.

HEALTHCARE PREMIUMS

Mr. FLAKE. Thank you. Madam Secretary, I want to follow up on a question that Jack Kingston talked about. This $2,500 reduction in premiums was not just one campaign promise tossed out once. It was said again, and again, and again, and again. I have actually 15 instances here of just in a few months where the President said we will start by lowering premiums by as much as $2,500 per family. Sometimes he said "by as much as," and other times just we will lower it by $2,500. I know you are saying that really cannot be accomplished until you have a State exchange, which we will not have until 2014.

Tell me, was that $2,500 promise a promise to lower premiums simply by shifting the cost to the taxpayer? And, if so, how does that jive with the budget figures and the assumptions that have been made going ahead? And if not, if it truly is a savings, tell me what is there inherent in this plan that drives down cost? I mean, there is not real competition that I can see. There is no tort reform. There are not requirements forcing insurance companies to compete across State lines. You just do not have things that typically in markets bring down costs.

So, I guess the first question is, is that $2,500 figure, is that savings or is that a cost shift to government, to taxpayers?

Secretary SEBELIUS. It is not a cost shift to government, Congressman. It is projected savings based on, again, not our analysis, but by the Congressional Budget Office.

I would disagree that there is not any competition. The new rules around an insurance exchange for the first time will introduce real competition into the insurance marketplace. They will have to compete for service and price as opposed to cherry picking, who might not get sick and could be included in programs. Consumers for the first time ever will have a very transparent way of making choices. They cannot be locked out or priced out of the market. And there is an estimation that there will be a serious reduction in overhead costs.

And we are already beginning to see some of that, glimpses of some of that with the 80/20 rule, the medical loss ratio, which requires companies for the first time in history to spend 80 cents out of every premium dollar on health expenses, not overhead costs.

And we are seeing companies begin to reposition and remarket. And for the first time in this calendar year, consumers will start to get rebates based on the fact that companies did not meet those costs estimates.

So, there are a series of steps. Small business may be the biggest winners because they are currently paying 18 to 20 percent more for exactly the same policy because they do not have any market leverage. They will be included in a larger pool by virtue of being part of an exchange. They will see cost reductions.

So, the cost reductions are real and based on competition, lower overhead costs, and the ability to be in a pool situation which most people cannot get unless they are in a large employer plan.

Mr. FLAKE. I am glad you mentioned the CBO because in 2008, the President promised his health care would cost between $50 and $65 billion a year when fully phased in. That is not what the Congressional Budget Office is saying. They are actually saying that Obamacare will cost $229 billion in 2020 and $245 billion in 2021.

What is responsible for the fourfold increase in projected cost?

Secretary SEBELIUS. Congressman, I do not know exactly what you are referencing. I would be glad to get you an answer very specifically in writing. But I really do not know what CBO numbers you are citing and what you are comparing them to. So, if you could provide those numbers then I would be delighted to get you an answer.

Mr. FLAKE. Let me just say in the time remaining, this assumption that we are going to get $2,500 in savings, net savings, not shift to the taxpayer when these exchanges start, is fanciful at best. I just do not know how to say it because nothing that has happened so far has suggested that there is anything really to drive down costs here. And I think that these are rosy assumptions.

I yield back.

Mr. REHBERG. Ms. Lowey.

TITLE X

Ms. LOWEY. Thank you, and welcome, Madam Secretary, and thank you for your important work. And I apologize, but I had an urgent meeting I had to run to.

An important component of health reform is the requirement that insurers provide free preventive services to women. Contraception we know is beneficial for women for a number of reasons, ranging from planned pregnancy to decreasing the risk of some cancers. In addition to the many health benefits, contraceptive coverage provides significant economic benefits for American families and the government.

It was really disappointing for me that the last two spending bills this subcommittee wrote, H.R. 1 from last year and Chairman Rehberg's draft Fiscal Year '12 bill, would have eliminated funding completely for the Title 10 Family Planning Program.

Can you share with us your views? Does reducing access to contraceptives increase overall health costs?

Secretary SEBELIUS. Well, Congresswoman, currently Title X serves about 5 million individuals a year who access Title X clinics. What we know is that they are often younger women. About 3 mil-

lion of them are under 25 years old. And comprehensive coverage includes both family planning and related reproductive and preventive health services, such as everything from HIV prevention, education screening, reduces not only unintended pregnancies, but infertility and related morbidity issues.

It is a health issue for both women and their families that has been enormously effective through the Title X program.

Ms. LOWEY. Thank you. I thought you were going to go on.

CDC GRANT CONSOLIDATIONS

I also want to talk to you about the CDC consolidation. In addition to concerns I have with the overall proposed funding level for the CDC, and along with the proposals Congress previously rejected to consolidate numerous programs, including chronic disease, birth defects, developmental disabilities, and environmental health.

I understand that the fiscal climate may make it difficult to fund disease-specific programs at the levels we might seek, but providing a relatively small amount of funding to specific diseases facilitates partnerships with national organizations that really do tremendous work improving public health.

I have spoken with Dr. Frieden about my concerns with consolidation, and I had hoped that the Administration would abandon its consolidation plan, particularly after Congress rejected the idea last year.

Could you tell us why the department is again proposing to consolidate so many programs within the chronic disease, birth defects, developmental disabilities, and environmental health accounts? What does it accomplish? Why is it a good idea?

Secretary SEBELIUS. Well, Congresswoman, I think a lot of the budget recommendations in the CDC budget are driven by conversations and consultation with our partners at the State level. And as you know, a lot of State public health budgets have been decimated over the last several years as resources have been slashed.

What we are trying to maximize is the flexibility at the State level to maximize public health impact by addressing public health needs, not in siloed programs, but in a flexible stream of funding where the States then can address their most pressing needs.

So, this recommends, as you say, consolidation of chronic disease, and birth defects, and developmental disabilities, asthma, and the Healthy Homes Program, in a way to try and use these resources as efficiently and effectively as possible to get to the public health goals I think we both share.

NATIONAL INSTITUTES OF HEALTH

Ms. LOWEY. Well, I hope we can continue that discussion because I think I strongly disagree with you on it.

Just briefly in the couple of, what, seconds, minutes I have left, the President talks about winning the future. And I agree that we have to prioritize investments that make sure more competitive. But it seems to me that investing in the NIH is absolutely essential. I would increase it because not only is it the global leader in innovative life-saving biomedical research, it supports more than

325,000 high paying research positions at more than 3,000 facilities across the country. So, I am sure we can all agree on that.

Why does the budget request not include an increase for the National Institutes of Health?

Secretary SEBELIUS. Again, Congresswoman, I think that NIH is about 40 percent of our Budget, and we are trying to maximize resources. Sharing your interest in biomedical research, what I can tell you is that the current Budget will allow the NIH to distribute about 672 new grants, about a 7.7 percent increase in grants. So, we will continue to enhance the research going on.

Thanks to the work with Congress last year, the new National Center for Translational Sciences is moving forward. The Cures Acceleration Network is moving forward. They both have additional resources in this year's Budget. So, Dr. Collins feels that this presentation, again, given our Budget restrictions, is the way to maximize grant opportunities, maximize strategic opportunities, and keep life-saving medicines moving forward.

Ms. LOWEY. Thank you. Thank you.

Mr. REHBERG. Secretary Sebelius, as we started late, I want to respect your time. Do you have a little additional time that you could stay? We figure that if we started the second round, as I look at the number of members here, it would take about a half an hour.

Secretary SEBELIUS. I do not have a half an hour, Mr. Chairman, I am sorry. I was told that 4:00 was the——

Mr. REHBERG. If you can grant us at least 10 minutes, I could ask an additional question and the ranking member, Ms. DeLauro, could ask an additional question. Can you grant us at least 10 minutes?

Secretary SEBELIUS. Yes, sir.

STRATEGIC NATIONAL STOCKPILE

Mr. REHBERG. Thank you very much.

First of all, and I may yield some of my time if you want to finish your questioning having to do with the lobbying, because I know I cut you off. But I wanted to ask you about the Strategic National Stockpile. And as you know, that is the preparedness providing resources, 12-hour push packages and managed inventory, chem packs, Federal medical stations.

And I noticed in the President's budget, and I am sensitive to this because I used to be a lieutenant governor. Disaster preparedness is something that has been very important to me. And I noticed that the President's budget proposes a reduction in the Strategic National Stockpile by 9 percent or $48 million in the Fiscal Year 2013. I just would like to have you explain how such a large reduction can possibly not impact the national preparedness posture.

Secretary SEBELIUS. The Budget request will allow the Centers for Disease Control and Prevention to replace the high priority expiring counter measures, such as small pox and antibiotics for the treatments of Anthrax. And that is one of the issues that we have to pay careful attention to—what is going out of stock.

But it will continue the ability to explore the methods of distribution, implement the national policy for Anthrax-related event, and

continue to purchase, and warehouse, and manage medical counter measures. So, we feel that this is an important initiative moving forward.

Mr. REHBERG. Thank you, Secretary. I am going to follow up with a letter——

Secretary SEBELIUS. Okay.

Mr. REHBERG [continuing]. Because I do want to address it in the larger bill. And so your staff has an opportunity to come up with an explanation or a description. I do not disagree necessarily. I just need to find out. I want to find out.

Secretary SEBELIUS. Sure.

Mr. REHBERG. Mr. Kingston, I will yield three minutes.

LOBBYING

Mr. KINGSTON. Thank you, Mr. Chairman.

Madam Secretary, we may need to just put these on the record, but I guess one of the questions is since the Philadelphia Department of Public Health was acting not in accordance with the law, I would like to know what happened, for example, if somebody abuses a grant like that, are they banned from getting future grants?

Secretary SEBELIUS. Mr. Kingston, I do not know that they did not act in accordance with the law. I do not know if they used their funding or Federal.

Mr. KINGSTON. Oh, I thought you said——

Secretary SEBELIUS. The law with regard to Federal funding being used for certain purposes.

Mr. KINGSTON. Okay. We will follow up with you on that then.

Secretary SEBELIUS. Sure.

SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM

Mr. KINGSTON. And now, on WIC, there is a limited menu. As you know, it is for nutrition, whereas on SNAP there is not. And I know that is not your jurisdiction. But recently, the USDA turned down the City of New York or New York City who wanted to try a limited menu for SNAP. And I would be interested in your thoughts about that, but only academically because I know it is not in your jurisdiction, or perhaps some of it is. I am not certain.

Secretary SEBELIUS. No, we do not have jurisdiction over the program.

Mr. KINGSTON. But if you had any thoughts along that line, that would be of interest to me.

And then I wanted to mention also, you do have some overlap on food deserts. You have an interagency working group or anything like that on food deserts?

Secretary SEBELIUS. The Department of Agriculture did some mapping, and we have a grant program that we run out of the agency——

Mr. KINGSTON. But you use the same definition.

Secretary SEBELIUS. Pardon me?

Mr. KINGSTON. You use the same definition?

Secretary SEBELIUS. We use their definition. We do not——

Mr. KINGSTON. Do you think that that definition should be revisited, because one of the things is that if you are in an urban area

a mile away from a grocery store, you are in a food desert, which I would think in so many cases is ridiculous. Have you looked at their definition?

Secretary SEBELIUS. We have, sir.

Mr. KINGSTON. And you think it is a good one?

Secretary SEBELIUS. Well, I think it is very difficult for a family buying groceries if they have to walk a mile with bags of groceries. It may be too far to get healthier food, so——

Mr. KINGSTON. You really think that.

Secretary SEBELIUS. I do.

Mr. KINGSTON. Because I suspect in this room most of us might live a mile away from a grocery store. And it is a broad——

Secretary SEBELIUS. And you walk a mile to get to the grocery store?

Mr. KINGSTON. Well, I do not think the walking part is in the definition.

Secretary SEBELIUS. Well, I am just suggesting to you, sir, that——

Mr. KINGSTON. But it is not in the definition, so, I mean, you know, it would also be bad if, you know, if you did not have a driver's license, but that is not in the definition, so that is not relevant.

Secretary SEBELIUS. We would be happy to look at the definition, but——

Mr. KINGSTON. I think we should in terms of the spirit of what a food desert should be. And I have interest in that, so let me yield back.

Mr. REHBERG. Okay. Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman.

Madam Secretary, I am going to try to get in two questions. I will be brief.

CONSUMER OPERATED AND ORIENTED PLANS

Co-op insurance plans, I know that the Affordable Care Act authorizes loans to set up these co-op health plans, to increase competition. These are non-profit -profit health insurance with customers making up the majority of the governing boards.

I understand you have just made 7 loans for startup costs, in New Mexico, Oregon, Iowa, Nebraska, Montana, New York, New Jersey, Wisconsin. There have been a number of attempts to reduce or eliminate funding for the co-ops. In the 2011 appropriations bill, $2.2 billion was rescinded. The 2012 Labor, HHS bill would have rescinded all remaining funding by shutting down the program before it made its first loan. In the final conference agreement we were able to considerably reduce the size of the rescission.

What is your view of the prospects for the co-op loan program? Is the department getting good applications? Do you think the program has promise? What would be the consequences of further rescissions?

Secretary SEBELIUS. Well, Congresswoman, it is designed to have competition in the marketplace, and as we have heard, that is a good thing. When monopolies exist among insurance companies, often it is very difficult to get pricing down. Competition tends to drive down prices. So, I think the program has great promise, and

we have had some good initial applications, and we look forward to more.

AFFORDABLE CARE ACT TRANSPARENCY PROVISIONS

Ms. DELAURO. I want to talk about transparency in the Affordable Care Act.

In 2009, less than 1 in 5 of the insurance plans that sold in the individual market included comprehensive maternity coverage. Now, maternity care is one of the 10 bundles of care that must be covered by plans as part of the essential health benefits package.

The agency announced groundbreaking transparency provisions. Plans that participate in the health insurance exchanges will have to use a helpful, concise, easy to understand summary of benefits coverage. I have an example of the form right here and the summary of important questions. Two clear examples of how the insurance plan would cover two things: having a baby and managing type 2 diabetes.

Can you tell me when the provision will be implemented? When will our constituents be able to use these helpful pieces of information instead of the hundreds of pages that the insurance company throws out at you and then you have to try to figure it out. Do you believe that it will help consumers make decisions about their health insurance options?

Secretary SEBELIUS. I do. A couple of things. I have just been told that the implementation for the transparency is October 1st of this year, so that the forms will begin to be revised, and folks will not have to wade through pages of small, fine print. And as a former insurance commissioner, I know how complicated that is for people to find out what actually their coverage includes.

We also, as you know, Ms. DeLauro, have in place right now in Healthcare.gov a website where for the first time consumers can get comparative information about plans, and deductibles, and prices in their own neighborhoods. That has never existed before, and we were directed to do that by the Affordable Care Act, and I think it has been an enormously important tool for people to find out about what they had in the marketplace, and how much it was going to cost before they went to an agent to try and buy insurance.

PREVENTION PUBLIC HEALTH FUND

Ms. DELAURO. Thank you for that. Also thank you on the anti-fraud measures. I think you have laid that out.

A final question, if I can get it in, and this is about the Prevention and Public Health Fund, which my colleagues keep talking about. But for the past two appropriations cycles, Congress has failed to exercise its authority to determine the uses of the fund. I believe that is because of a reluctance on the part of some of our majority colleagues to have anything to do with anything connected in any way with the Affordable Care Act. As a result, the priority setting for the Prevention and Public Health Program has been turned over to the executive branch.

Tell us your approach, what that has been, to allocating and using amounts of the Prevention and Public Health Fund. What have you accomplished and what do you hope to accomplish in 2013? You are not going to have a chance to answer all those ques-

tions. We can follow up. But at least what is your approach, and what do you think you have accomplished?

Secretary SEBELIUS. Well, I think the approach is, as it was designed, to focus on strategies that actually reduce health costs and create a healthier population. Tobacco prevention, the new Community Transformation Grants, which are focusing on enormously promising health strategies, HIV/AIDS work, public health workforce, State epidemiology and laboratory capacity, coordinated disease prevention, are all areas that have been funded. And we would look forward to working with Congress on the allocation.

As you know, since there was no directed allocation by the Appropriations Committee, we did have informal conversations with bipartisan staff members from both the Appropriations Committees in the House and Senate. I tried as much as possible to follow their direction, but look forward to having those conversations in the future.

Ms. DELAURO. Thank you. Thank you, Madam Secretary. Thank you for the job you are doing.

Mr. REHBERG. Thank you.

Members are allowed 14 days to submit questions for the record.

Mr. REHBERG. Secretary Sebelius, I thank you for making your presentation today, for being patient with us, and giving us a little extra time. Thank you.

Secretary SEBELIUS. Certainly.

Department of Labor, Health and Human Services and Education and Related Agencies

Department of Labor FY13 Budget Request Hearing
March 6, 2012

QUESTIONS FOR SECRETARY SEBELIUS
TO BE SUBMITTED FOR THE PUBLIC HEARING RECORD

HHS Questions for the Record
From Chairman Rehberg

LIHEAP
Madame Secretary, I noted that you are requesting $625 million less for the Low Income Home Energy Assistance (LIHEAP) program for fiscal year 2013. And yet, you are requesting $200 million more for a contingency fund. Given the difficult economic times many families are facing today, it would seem that this assistance is all the more critical to maintain. Please explain your reasoning for this cut and what you believe the impact will be on those in need of energy assistance?

Answer: The President's Budget adjusts the LIHEAP request to reflect recent fuel cost trends and targets funds to those most in need. The Budget requests $3.02 billion for LIHEAP, $452 million below the FY 2012 enacted level, but $450 million above previous years and the President's FY 2012 request, reflecting an adjustment for rising heating oil costs. The Budget also proposes to target base funds using the same State allocation Congress enacted in 2012, providing about 85 percent of base funds through a statutory formula favoring colder States and States that are more reliant on heating oil.

In addition, the President's Budget sets aside $200 million of the total request for a contingency fund. The Administration anticipates using to address the needs of heating oil households should oil prices remain high and for other energy-related weather emergencies.

Consumer Operated & Oriented Plan (CO-OP)
The Department of Health and Human Services (HHS) received $6 billion in ObamaCare funds for a new program, the Consumer Operated & Oriented Plan (CO-OP) program, to provide what are essentially federally-subsidized loans to establish new insurance companies which will participate in the federal health exchanges.

This program essentially moves HHS into competition with health care venture capitalism and banking organizations. We have heard the average loan under this program will be around $50 million or more and have a federally subsidized 15 year pay-back period with interest rates at 1 to 2 percent below the Treasury rate. At today's rates, it seems like essentially free money.

I am concerned HHS does not have the venture capitalist or banking expertise required to effectively manage this program. In the July 20, 2011 proposed rule to establish this program, HHS acknowledged the program loan repayment would only be "65 percent of the Solvency Loans and 60% of the Start-Up Loans."

This estimated default rate will cost taxpayers $350 to $400 million for every $1 billion made in loans—not likely a successful business model.

Interestingly, the President's solvency estimate was removed in the final rule, however -- based on what seems to be accounting gimmicks and rosy estimates of the probable success of these risky business ventures.

Since there will be between 50 to 100 of these CO-Ops or HHS-blessed insurance companies to compete with other insurers for business—there is certainly a lot of money being put at risk.

- **Please explain how HHS is likely to have such great success at picking successful new insurance companies when the agency has no expertise in doing so?**

Answer: The Department takes very seriously the responsibility to protect taxpayer funds invested in CO-OPs with viable business plans, which is designed to foster the development of consumer-governed, private , non-profit health insurance issuers- thereby improving consumer choice and plan accountability, promoting integrated models of care and enhancing competition in the Affordable Insurance Exchanges. As discussed in the preamble of the CO-OP final rule, CO-OP loans will only be made to private, non-profit entities that demonstrated a high probability of becoming financially viable. To date, a total of 10 non-profits offering coverage in 10 States have been awarded $845,012,408 through the CO-OP program To assist CMS in awarding CO-OP loans, we have qualified expert, objective technical panels review applications and provide recommendations to CMS staff. The technical review panels review all applications to determine applicant eligibility based on factors including financial viability, and applicants are required to submit a feasibility study and business plan. In addition, an objective CMS Selection Committee comprised of insurance and actuarial experts reviews the recommendations made by the panel and issues a formal agency determination. As discussed in the preamble of the final rule and under the terms and conditions of the loan agreement, loan recipients will be subject to strict monitoring, audits and reporting requirements for the length of the loan repayment period plus 10 years and CO-OPs must meet a series of milestones before drawing down disbursements

- **Given that HHS is operating as a venture capitalist and a bank, how does HHS ensure it complies with the Dodd-Frank and other credit reform measures to ensure tax payers are fully paid back?**

Answer: The CO-OP program is one of many loan programs operated by the Federal government. Established in Section 1322 of the Affordable Care Act, the purpose of the CO-OP program is to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets. CO-OPs are expected to improve competition, consumer choice, plan accountability and patient care. .

The appropriation was provided to subsidize and encourage this new activity through tools such as below market interest rates.

In addition, the CO-OP program contains extensive provisions to protect against fraud, waste, and abuse. Loan recipients are subject to strict monitoring, audits, and reporting requirements for the length of the loan repayment period plus 10 years. Recipients will submit semi-annual program reports and quarterly financial statements. Additionally, CMS will conduct audits including site visits, as appropriate. CO-OPs must meet a series of milestones as laid out in their loan agreements before drawing down any money from the program and in advance of subsequent draw downs.

If a loan recipient fails to meet certain provisions of the CO-OP program or their loan agreement and has not corrected such failure, the organization must repay an amount equal to 110 percent of the total loans received, plus interest.

- **Explain the safeguards HHS created after the draft rule was released to eliminate the risk from the initial solvency estimate in the proposed rule to protect tax payer money?**

Answer: The default rate discussed in the CO-OP proposed rule (76 FR 43237) is very different from a potential CO-OP insolvency. The Department is required to estimate net federal benefits, costs, and transfers associated with this rule in the regulatory impact analysis (RIA). It was estimated that a certain percentage of CO-OPs would not pay back their loans within a certain time period. This is not an estimate of insolvencies. The RIA did not estimate insolvencies.

The Affordable Care Act, in section 1322, requires the repayment of loans, but repayment terms "must take into consideration any appropriate State reserve requirements, solvency regulations, and requisite surplus note arrangements." The statute envisions occasions, such as when a loan recipient must keep additional State-mandated insurance reserve requirements, when it is in the best interest of the consumer, loan recipient, and the State regulator for Department to change the loan repayment terms. This is an example of a situation that may result in a loss, but does not constitute insolvency.

The money appropriated is designed to provide a subsidy to encourage this new activity, and the subsidy rate reflects factors such as the below market interest rates and other terms and conditions of the loans to encourage establishment of non-profit, consumer-governed issuers and increase competition and choice in the market.

- **What happens to these loans if the Supreme Court overturns the mandate?**

Answer: HHS is confident that the Affordable Care Act is constitutional and we will continue to implement the law. We are currently continuing to focus on providing the benefits and protections of the law to the American people.

Rolling Back Lobbying Restrictions

During the FY 2011 budget hearing in 2010 you told us, and I quote: "I can assure you that we will follow to the letter of the law the Federal law which prohibits Federal funds and has, not just in the Recovery Act but consistently, prohibited lobbying with Federal dollars. We will track that very carefully. We have already notified a whole host of folks that that is the law of the land. That was part of the grant application and will continue to be part of the monitoring. Federal funds will not be used for lobbying."

It is good to know we both support following funding restrictions and the law. As you know, anti-lobbying restrictions have been included in appropriations bills for as long as I can recall. However, I was deeply concerned the President's FY 2013 budget proposal asks Congress to eliminate or reduce some of these restrictions that were included in the FY 2012 Omnibus.

Specifically, the President would significantly reduce Section 503 of the FY 2012 Omnibus. The revision in the request eliminates significant safeguards on using federal funds to lobby. It effectively would allow the use of federal funds to defeat proposed or pending regulations, administrative action, or orders issued by State or local governments.

Please explain why the President wants Congress to reverse decades of precedent by eliminating this language, effectively allowing the use of federal dollars to fund lobbying campaigns?

Answer: HHS is committed to ensuring the proper use of appropriated funds, and to ensuring awardees' compliance with all applicable regulations and statutes related to lobbying activities, such as Office of Management and Budget (OMB) Circular A-122: Cost Principles for Non-Profit Organizations; OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Governments; our own policy regarding lobbying activities; and 18 U.S.C. § 1913: Lobbying with Appropriated Moneys.

For the FY 2013 President's Budget, a review was conducted of general provisions of the FY 2012 Consolidated Appropriations Act, including Section 503. Provisions deemed duplicative of existing law were removed. HHS programs have required grantees to comply with all existing laws in using federal funds.

HHS awardees are informed about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. Not only are the restrictions noted within HHS funding opportunity announcements, the lobbying prohibition is also included within the terms and conditions to which each awardee agrees prior to receiving federal funds. Violations of grantee terms and conditions may result in actions such as restriction on award, special monitoring procedures, or award termination.

In addition, HHS staff monitor the use of federal funds by awardees using tools such as on-site review and risk mitigation plans. HHS staff regularly interact with grantees to ensure that they are implementing the activities and strategies set forth in the grantee's work plan and that grantees are adhering to administrative requirements, including adhering to provisions relating to lobbying.

Applicable lobbying restrictions do not prohibit awardees from interacting with policymakers. Federal law allows many activities that are not considered lobbying and that community awardees may decide to pursue. For example, awardees may use funds to disseminate information about public health programs and science-based solutions and to implement specific programs, such as evidence-based educational materials and media on the health effects of increasing physical activity or decreasing exposure to secondhand smoke. However, it would not be permissible for awardees to influence, directly or indirectly, a specific piece of pending legislation.

At HHS, we are committed to fulfilling the mandates from Congress to empower communities to pursue high-quality, science-based programs that make a real difference in the health of Americans. We take our responsibility as stewards of taxpayer dollars very seriously, and we are committed to enabling awardees' success and to ensuring that federal funds are used efficiently and appropriately.

Rural Health Programs

The request proposes to cut the Rural Health Programs under the Health Resources and Services Administration by $15.9 million. The rural areas of our country have been hit particularly hard during the economic decline of the last few years.

- **How can you justify such a large decline in funding for such areas?**

Answer: The Budget includes carefully considered reductions that redirect funding to more direct service activities. The decline in funding for rural health programs is primarily the result of the discontinuation in
FY 2013 of the Small Hospital Improvement Program (SHIP). In FY 2012, the SHIP program was funded at $14 million. The Affordable Care Act provided enhanced payments to rural hospitals paid under the Medicare Inpatient Prospective Payment system. In addition, 1,300 of the approximately 1,600 hospitals eligible for funding through the SHIP are Critical Access Hospitals (CAHs) and, as such, have access to the funding from the Medicare Rural Hospital Flexibility Program.

- **What do you believe will be the impact of this $15.9 million cut?**

Answer: The reduction to the Rural Health Hospital Flexibility Grant Program is a $16 million reprioritizing of funding to programs that provide direct services in rural and underserved communities. The decline in funding for rural health programs is primarily the result of the discontinuation in FY 2013 of the Small Hospital Improvement Program (SHIP). In FY 2012, the SHIP program was funded at $14 million. The Affordable Care Act continues to support inpatient and outpatient services. The Affordable Care Act provides enhanced payments to rural hospitals paid under the Medicare Inpatient Prospective Payment system. In addition, 1,300 of the approximately 1,600 hospitals eligible for funding through the SHIP are Critical Access Hospitals (CAHs) and, as such, have access to the funding from the Medicare Rural Hospital Flexibility Program.

Rural and Community Access to Emergency Devices Program
The President's request provides no funding for the Rural and Community Access to Emergency Devices Program. This program supports the procurement of automated external defibrillators (AEDs) for communities to ensure that these life saving devices and trained individuals are available at public gatherings. These devices can double the odds of survival – particularly in rural areas that are far removed from hospitals. Given the large incidence of cardiac arrest in this country, it would seem that the availability of these devices in rural areas is critical.

Please explain the rationale behind the funding elimination for this program. Is it a matter of every rural area in the country having an AED available?

Answer: The decrease in funding reflects a reprioritization of these funds to other activities within the Office of Rural Health. Since the creation of the program in FY 2002, the Rural Access to Emergency Devices program has invested approximately $32 million in rural communities to purchase, place and train providers to use AEDs. Approximately 8,000 AEDs have been placed in rural communities and 47,827 laypersons and responders have been trained since FY 2007, with numbers increasing each year. Funds for the purchase, placement and training of providers to use AED's are also available through the Rural Health Care Services Outreach grant program. This program funds direct health care services in rural communities with the community identifying the needed services. The U.S. Department of Agriculture (USDA) Rural Development also supports grant and loan programs for equipment purchase in rural communities.

Children's Hospitals Graduate Medical Education Program
The President's request provides only $88 million for the Children's Hospitals Graduate Medical Education (GME) Program. In FY12, the President's budget provided no funding for the GME. The FY13 funding request is apparently intended to cover only the direct costs of supporting the residents, leaving the Children's hospitals responsible for covering all of the indirect costs of providing medical residencies. Because the Children's Health Insurance Program only reimburses direct costs at a rate of 80%, Children's hospitals are already at a disadvantage. Add in the additional costs of supporting the education of residents and that disadvantage increases further.

Please explain how the Department rationalizes this reduction in funding.
We recognize the vital role that children's hospitals and pediatric providers play in providing quality health care to our Nation's children.

Answer: The FY 2013 Children's Hosptials Graduate Medical Education (CHGME) funding level continues to support direct costs for training pediatric residents at independent children's hospitals. This covers the costs of resident salaries, expenditures related to stipends and fringe benefits for residents, salaries and fringe benefits of supervising faculty, cost associated with providing the GME training program, and allocated institutional overhead costs.

The FY 2013 Budget retains the incentive to maintain total resident levels. Additionally, The FY 2013 President's Budget includes $5 million to implement the Pediatric Specialty Loan

Repayment (PSLR) Program that was authorized in the Affordable Care Act. Under this program, loan repayment agreements will be authorized for pediatric specialists who agree to work in underserved areas.

While both the CHGME Payment and the PSLR programs support the pediatric medical workforce, each of these programs has a different focus . The CHGME Payment Program serves the purpose of providing residency training in Children's Hospitals through the payments made to Children's Hospitals, while the PSLR program is designed to assist pediatric specialists more directly and increase the number of pediatric specialists in underserved areas.

"Million Hearts Campaign"
Over the past year, HHS announced its "Million Hearts Campaign", a national initiative to prevent 1 million heart attacks and strokes over five years. The campaign, as it was described in news coverage in the New England Journal of Medicine, appropriately focuses on several risk factors, one being high blood pressure. However, the article's focus regarding controlling blood pressure seems to be primarily directed at lowering sodium intake, rather than the other known factors.

It seems the comments and advocacy for lowering sodium intake may not addressed some troubling questions raised in recent scientific publications. Such papers, three over the past year alone, seem to raise serious concerns as to the safety and efficacy of even modestly reduced sodium diets.

These papers appear to independently identify a significant increase in mortality associated with even a modest reduction in sodium intake. Compared to those individuals consuming a normal sodium intake, a subject eating a modestly reduced amount of sodium or salt had a risk of death that was 50% to 200% greater. It appears that statistical analysis isolated this dramatic increased risk of death solely to a lower sodium diet. These three reports, listed below, are the first to follow large cohorts of subjects prospectively over a long period of time, measuring their sodium intake and recording the most important health outcome: causes of death.

It appears that two of the studies show increased mortality were in patients with diabetes, one studied type 1 diabetics and the other type 2, makes the findings even more concerning.

As you can appreciate, a public policy of lowering the salt intake of all Americans, and in the case of school lunch specifically, children, must be one that has been unequivocally proven to be both safe and effective, a standard the current medical literature does not appear to support.
Please explain how these studies have or will impact any policies across HHS organizations that impact public health. Also, we would appreciate it if you would review the findings in these reports and provide your analysis.

- **Stolarz-Skrzypek K, Kuznetsova T, Thijs L, et al. Fatal and nonfatal outcomes, incidence of hypertension, and blood pressure changes in relation to urinary sodium excretion. JAMA 2011; 305:1777-85.**
- **Thomas MC, Moran J, Forsblom C, et al. The association between dietary sodium intake, ESRD, and all-cause mortality in patients with type 1 diabetes. Diabetes Care 2011; 34:861-6.**
- **Ekinci EI, Clarke S, Thomas MC, et al. Dietary salt intake and mortality in patients with type 2 diabetes. Diabetes Care 2011: 34:703-9.**

Answer: The Million Hearts initiative focuses on both clinical and community prevention to prevent one million heart attacks and strokes across the nation over five years. Clinically, the initiative focuses on improving the "ABCS" of preventive care: appropriate Aspirin Use, Blood Pressure control, Cholesterol management, and Smoking cessation. The referenced September 2011 New England Journal of Medicine article provides several examples of how blood pressure control and the other clinical priorities are promoted through Million Hearts, including improved usage of health information technology to track patient progress on blood pressure and clinical innovations that prioritize improving performance on blood pressure control. It is also true that one of the Million Hearts community prevention priorities is the promotion of sodium intake reduction.

The 2010 Institute of Medicine report "Strategies to Reduce Sodium Intake in the United States" calls for gradual stepwise reduction in the sodium intake of all Americans with evaluation and readjustment after each step. We agree that continued monitoring of this approach is essential for both effectiveness and safety. CDC and FDA are working together to enhance current monitoring of both intake and health outcomes of dietary sodium intake.

The studies listed (Stolarz-Skrzypek et al., 2011; Thomas et al., 2011; Ekinci et al., 2011) are all observational studies. Observational studies are useful for generating hypotheses – that is, developing scientific research questions. However, a significant limitation of their design is that study subjects are not randomly assigned to either the control or experimental group, and the study is subject to bias. Therefore, any observed associations between the exposure and the outcome (in this case sodium and mortality) cannot be interpreted as causal relationships. There are additional methodological issues with these studies that might skew the results to appear that there is no association between sodium intake and blood pressure. In particular, across the three studies, researchers did not account for the influence of physical activity and inadequate measurement of long term sodium intake.

None of the three studies controlled for the confounding effect of physical activity in their data analysis. In general, people who are more physically active generally eat more food and therefore have higher sodium intake. Physical activity reduces the risk of cardiovascular disease. As noted by researchers at Harvard University (http://www.hsph.harvard.edu/nutritionsource/salt/jama-sodium-study-flawed/index.html), lack of control for physical activity could make it appear that higher sodium intake protects against cardiovascular disease deaths when in fact the observed association is explained by the confounding effect of physical activity.

Additionally, a second significant limitation is the measurement of sodium intake. Use of either a single 24-hour urine collection (Thomas et al, 2011; Stolarz-Skrzypek et al, 2011) or even the average of a few measurements (Ekinci et al, 2011) does not represent a person's usual long term sodium intake. Diet varies from day-to-day and over time. A 24-hour urine collection reflects sodium intake over about one day. Using one measurement, or the mean measurement of a few days' samples, of 24-hour urine collection can erroneously place a person with low or high sodium intake in the wrong category with paradoxical results.

These and other methodological issues are discussed in the following letters to the editor:

- Cook NR. Urinary sodium excretion and cardiovascular disease mortality. JAMA. 2011 Sep 14;306(10):1085.
- de Abreu-Silva EO, Marcadenti A. Urinary sodium excretion and cardiovascular disease mortality. JAMA. 2011 Sep 14;306(10):1085-6.
- Bochud M, Guessous I, Bovet P. Urinary sodium excretion and cardiovascular disease mortality. JAMA. 2011 Sep 14;306(10):1084.
- Labarthe DR, Briss PA. Urinary sodium excretion and cardiovascular disease mortality. JAMA. 2011 Sep 14;306(10):1084-5.
- Aleksandrova K, Pischon T, Weikert C. Urinary sodium excretion and cardiovascular disease mortality. JAMA. 2011 Sep 14;306(10):1083.
- Rebholz CM, He J. Urinary sodium excretion and cardiovascular disease mortality. JAMA. 2011 Sep 14;306(10):1083-4; author reply 1086-7.
- Heerspink HJL, Kwarkernaak A, de Zeeuw D, Navis G. Comment on Ekinci et al., Dietary salt intake and mortality in patients with type 2 diabetes. Diabetes Care 2011;34:e124.

The three studies cited do not refute the consistent evidence from animal studies, human genetic studies, methodologically strong observational studies, and randomized controlled trials indicating a clear positive effect of salt reduction on lowering blood pressure. Because of the weight of evidence demonstrating that excess sodium has a significant negative impact on high blood pressure, numerous professional health organizations, including the American Heart Association, the American Medical Association, and the American Public Health Association, support dietary

Dietary Guidelines on Sodium

On a number of occasions you and your agency have been made aware of the overwhelming number of peer-reviewed medical studies recently published which have cautioned against population-wide salt reduction [i,ii,iii,iv,v,vi,vii], including the latest one demonstrating that anyone who follows the 2010 Dietary Guidelines for sodium will end up with a highly unbalanced and nutritionally inadequate diet. This evidence leads many to conclude that the Dietary Guidelines on Sodium are in violation of the statute (The National Nutrition Monitoring and Related Research Act) that mandates that they be based on the "preponderance of the scientific and medical knowledge." Does the Administration plan to revise the Dietary Guidelines on Sodium to a higher level in light of the weight of the research? And given the research does the Administration plan to halt the implementation of any population-wide sodium reduction strategies that may, in fact, harm the citizens of the United States?

Answer: Reducing sodium intake remains an important strategy to improve public health. The studies footnoted in the article do not refute the preponderance of scientific evidence supporting the conclusion that sodium reduction has a positive effect on reducing blood pressure. As expressed in the response to the previous question, there is a long-standing and expanding collective body of evidence finding that, for the majority of the population, blood pressure is reduced when sodium intake is reduced. Similarly, eating greater amounts of sodium is associated with higher blood pressure and a greater risk of cardiovascular disease. Maintaining blood pressure in the normal range reduces an individual's risk of cardiovascular disease, congestive heart failure, and kidney disease. More than 800,000 Americans die each year from heart disease and stroke – both are leading causes of death. Moreover, heart disease and stroke cost the nation $273 billion in healthcare costs each year.

The recommendations of the *Dietary Guidelines for Americans* (DGA) released every 5 years by HHS and USDA are the result of a three stage process:

- During the first stage, an external scientific Dietary Guidelines Advisory Committee (DGAC) is appointed to conduct an analysis of new scientific information on diet and health and prepare a report summarizing its findings. The 2010 DGAC used a systematic evidence-based methodology to facilitate its review of the scientific literature and address approximately 130 scientific questions. The methodological rigor of each study included in the analysis was assessed, and the body of evidence supporting each question was summarized, synthesized, and graded by the Committee. The DGAC report was made available to the public and Federal agencies for comment.
- The second stage consisted of development of the document entitled *Dietary Guidelines for Americans,* which is based upon (1) the Advisory Committee's report and (2) consideration of public and Federal agency comments.
- In the third and final stage, messages and materials are developed for communicating the DGA to the public.

In addition to the footnoted studies, another study is referenced in the question by the phrase "including the latest one demonstrating that anyone who follows the 2010 Dietary Guidelines for sodium will end up with a highly unbalanced and nutritionally inadequate diet." It is our assumption that the study being referred to was authored by Mailot and Drewnoski (*Am J Prev Med* 2012; 42(2):174-9), which considered current food patterns of typical American consumers. It is important to note that the observed diets of the typical American consumer and the participant data used to model food patterns in the study are not generally consistent with *Dietary Guidelines for Americans* recommendations. Specifically, the observed diets are high in meats and refined grains and relatively low in vegetables, fruit, dairy, beans and nuts, and whole grains. Importantly, it is not the charge of the *Dietary Guidelines for Americans* to develop recommendations that model existing American consumption patterns, but rather to improve the health of our Nation's current and future generations by facilitating and promoting healthy eating and physical activity choices so that these behaviors become the norm among all individuals. The *2010 Dietary Guidelines for Americans* specifically note that sodium reduction is a long-term goal. As sodium is gradually reduced in the food supply, consumers will have more choice and control when it comes to their personal sodium intake (e.g. if they choose to consume a low-

sodium diet or add salt to taste) and more available options to assist them in maintaining adequate levels of other nutrients while on a lower sodium diet.

Future recommendations by the *Dietary Guidelines for Americans* will continue to reflect the totality of research and be made based on what's best for public health. Additionally, CDC is working with other federal agencies to continue to assess the scientific evidence related to sodium (considering what conclusions can be drawn based on study designs and analysis) and to review and consider comments received by USDA/FSIS and HHS/FDA as part of their sodium-related dockets (FDA-2011-N-0400 and FSIS-2011-0014).

Pandemic and All Hazards Preparedness Act of 2006

A key objective of the Pandemic and All Hazards Preparedness Act of 2006 (PAHPA) was to ensure continued involvement of innovative biotechnology companies in the badly underserved biodefense sector. Yet, we understand BARDA has informed companies willing to develop their products to address high priority threats that there will be no new Advanced Research & Development (AR&D) contracts in FY 2012 and possibly FY 2013 due to prior commitments. Please explain how BARDA can justify this position in the face of the goals of PAHPA?

Answer: Given the length of time and high cost it takes to develop a new pharmaceutical product, which on average requires eight to ten years and up to one billion dollars, the Biomedical Advanced Research and Development Authority (BARDA) has endeavored since its inception six years ago to support the highest priority medical countermeasures along the early development to advanced development pipeline, while operating within budget constraints. Contracts for medical countermeasure development are solicited and awarded in accordance with the strategy developed by the Public Health Emergency Medical Countermeasure Enterprise, which includes representation from the Department of Homeland Security, Department of Defense, and the Department of Health and Human Services and in accordance with the National Health Security Strategy, and relevant Presidential Directives, Homeland Security Directives and the stated goals of the Pandemic and All-Hazards Preparedness Act. BARDA contracts for advanced development research are typically awarded for a period of five years. While the Department greatly values the expansion of our medical countermeasures portfolio, we must make good on our existing contracts before soliciting any new ones, particularly as current BARDA and Project BioShield resources are set to expire at the end of FY 2013. BARDA contracts which may continue in FY 2012 and FY 2013 will support high priorities medical countermeasures necessary for National preparedness. In FY 2013, the President's budget requests $546 million for BARDA, an increase of $132 million. These funds would be used to continue and expand the Department's medical countermeasure program and further National preparedness by moving countermeasures from early to advanced development and eventually to procurement and stockpile.

BARDA Priorities

Please explain the criteria and strategy used by BARDA to invest taxpayer funds to address the many bioterrorism threats facing our country?

BARDA prioritizes the development and procurement of medical countermeasures for the highest risk threats, including pandemic influenza and terrorist use of chemical, biological,

radiological, or nuclear materials. The Pandemic and All-Hazards Preparedness Act called for the public health and medical needs of at-risk individuals to be taken into account in developing a national stockpile of medical countermeasures. Consistent with statutory requirements, BARDA supports the advanced development of medical countermeasures for all populations, with the goal of making them available for use as needed during public health emergencies.

BARDA's CBRN programs have focused on developing medical countermeasures to meet the requirements determined to be necessary to address the 13 Material Threats identified by the Department of Homeland Security in accordance with Project BioShield. BARDA's influenza program has contributed to pandemic preparedness by supporting the development of improved and/or next-generation influenza vaccines, antiviral medications, ventilators, and other non-pharmaceutical countermeasures; stockpiles of pre-pandemic vaccines and antiviral medications; and increased domestic influenza vaccine manufacturing capacity. More recently, BARDA has begun to address the threat of antimicrobial resistance, emerging infectious diseases, and other novel threats by initiating programs supporting the development of broad-spectrum antimicrobials and technologies and platforms with multi-use potential. BARDA will maintain this three-pronged focus on CBRN threats, pandemic influenza, and emerging infectious diseases, modifying its current portfolio as needed to (1) ensure that the medical countermeasure needs of all populations are addressed and (2) enhance long-term sustainability of our preparedness posture.

Anthrax

We have heard some homeland security advisors suggest that HHS should allow anthrax vaccine from the Strategic National Stockpile be made available for voluntary pre-event vaccination of emergency responders. Does HHS have any views on this suggestion and what the cost would be?

Answer: First responders are the backbone of State and local response to natural and man-made disasters. Recognizing the potential risks for first responders during a bio-terror incident, the Department of Health and Human Services has been actively coordinating with our Federal partners in consideration of pre-vaccination for first responders against certain biological threats.

Additionally, the Centers for Disease Control and Prevention (CDC) is currently partnering with the Department of Homeland Security in a joint pilot program to offer voluntary, pre-event anthrax vaccinations to first responders. The CDC is committing vaccine and shipping, at no charge, to one location per Project Area or State in the pilot program. While the costs for this project are still under development, CDC is committed to assuring that this is not a barrier to the pilot effort.

Community Transformation Grants (CTG)
In September 2011, HHS / CDC awarded $107 million in Community Transformation Grants (CTG). Today, 5 months after the grants were announced, we still have no idea how that $107 million is being spent by the recipient communities. All we know is that the grants will "focus on expanding efforts in tobacco-free living, active living and healthy

eating, quality clinical and other preventive services, and healthy and safe physical environments".[1] All of the grants were given this same description on the CDC's website.

For 2012, the CDC plans to distribute $226 million in CTG grants. For 2013, the President's budget has $146 million slated for CTG grants. Over three years, that totals more than $475 million in CTG grants that Congress isn't being told much about. In 2010, we know that the CDC spent hundreds of millions of dollars on a similar grant program that carried out lobbying campaigns, anti-food propaganda, and other questionable activities. For example, grantee reports explained how funds were being used to:

- **"advance policy changes that address the sale of sugar-sweetened electrolyte replacement beverages"[2] and "write a legislative concept paper...sent forward to the Governor for consideration..."[3]**
- **"Reduce density of fast food establishments and convenience stores without healthy food options" ... and ... "enact a moratorium on new drive-throughs."[4]**
- **Hire a "grassroots coordinator" who spent "163 hours" and is responsible for "establish[ing] community support by educating and advocating for the adoption of smoke-free policies."[5]**
- **"seek sponsorship of bill that increases excise tax on other tobacco products..."and conduct "meetings with policy makers." Grantees state that the strategy they are using is a "similar strategy that was used in getting the Clean Indoor Act passed in the legislature in 2002."[6]**

Are similar activities planned for the CTG grants distributed in 2011, and the ones planned for 2012?

Answer: Chronic diseases such as heart disease, cancer, and diabetes are the leading causes of death and disability in the United States, accounting for 70 percent of all deaths. These diseases cause major limitations in daily living for about one out of ten Americans. Chronic diseases are also costly, accounting for approximately 75 percent of the $2.5 trillion our nation spends annually on health care. Yet chronic diseases are also among the most preventable. Lack of physical activity and poor nutrition—two modifiable risk factors for obesity—and tobacco use are responsible for much of the illness, suffering, and death related to chronic diseases.

The Community Transformation Grants (CTG) program builds upon CDC's experience improving community health and marks the next stage of CDC's commitment to community-based programs. The CTG program supports states and communities to develop and implement initiatives that prevent chronic diseases, the leading causes of death and disability. CTGs focus on five strategic priority areas: 1) tobacco-free living, 2) active living and healthy eating, 3)

[1] http://www.cdc.gov/communitytransformation/funds/programs.htm#implementation
[2] /www recovery gov/Transparency/RecipientReportedData/pages/RecipientProjectSummary508 aspx?AwardIdSur=93811&AwardType=Grants
[3] www recovery gov/Transparency/RecipientReportedData/pages/RecipientProjectSummary508 aspx?AwardIDSUR=93811&qtr=2010Q3
[4] www recovery gov/Transparency/RecipientReportedData/pages/RecipientProjectSummary508 aspx?AwardIDSUR=97369&qtr=2010Q2
[5] www recovery gov/Transparency/RecipientReportedData/pages/RecipientProjectSummary508 aspx?AwardIdSur=99046&AwardType=Grants
[6] http://recovery delaware.gov/documents/grant-applications/Funding_for_Healthy_Communities pdf

increased use of high-impact clinical preventive services to prevent and control high blood pressure and high cholesterol, 4) social and emotional wellness, and 5) healthy and safe physical environments. CTG grantees must align their efforts with the following program objectives:

- Reduce death and disability due to tobacco use by 5 percent in the implementation area.
- Reduce the rate of obesity through nutrition and physical activity interventions by 5 percent in the implementation area.
- Reduce death and disability due to heart disease and stroke by 5 percent in the implementation area.

Community Transformation Grant (CTG) awards were announced in September 2011. Sixty-one states and communities received awards. Thirty-five states and communities will implement evidence- and practice based programs designed to improve health and wellness. Twenty-six states and communities will work to build capacity to implement changes by laying a solid foundation for community prevention efforts to ensure long term success. Seven national networks of community based organizations were also funded. The four dissemination awardees will work to disseminate CTG strategies within their national network of local affiliates. The three acceleration awardees will support local communities in assessing and addressing CTG health priorities. Through this effort, more than 1 in 3 U.S. citizens are being reached, including more than 20 million Americans in rural and frontier areas.

Plans for the 2012 increase in CTG funds are currently under development.

Please explain how these activities not direct violations of federal anti-lobbying prohibitions?

Answer: HHS is committed to ensuring the proper use of appropriated funds, and to ensuring awardees' compliance with all applicable regulations and statutes related to lobbying activities, such as 18 U.S.C. § 1913: Lobbying with Appropriated Moneys; Office of Management and Budget (OMB) Circular A-122: Cost Principles for Non-Profit Organizations; OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Governments; and our own policy regarding lobbying activities. CDC's policy prohibits lobbying at the federal, state, and local levels. These restrictions apply to CDC grants, including CTG program.

HHS awardees, including those in the CTG program, are informed about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. Included within the respective funding opportunity announcements for the CTG program is Additional Requirement 12, "Lobbying Restrictions" (AR-12). AR-12 states CDC's policy prohibiting awardees from using any appropriated federal funds for "any activity designed to influence action in regard to a particular piece of pending legislation." This lobbying prohibition was also included within the terms and conditions to which each grantee agreed prior to receiving federal funds. In addition, CDC staff have conducted trainings for CTG awardees on these prohibitions.

Applicable lobbying restrictions do not prohibit awardees from interacting with policymakers. Federal law allows many activities that are not considered lobbying and that community awardees may decide to pursue. For example, awardees may use funds to disseminate

information about public health problems and science-based solutions and to implement specific programs, such as evidence-based educational materials and media on the health effects of increasing physical activity or decreasing exposure to secondhand smoke.

We take our responsibility as stewards of taxpayer dollars very seriously. CDC staff interact with awardees regularly to monitor implementation of the activities and strategies set forth in awardees' work plans and compliance with administrative requirements, including provisions related to lobbying. In addition, CDC staff monitor the use of federal funds by awardees using tools such as on-site review and risk mitigation plans.

We are reviewing each of the examples. Thus far, we have not found among these examples any instance in which the anti-lobbying prohibitions have been violated. Several of the statements were reporting on activities that were performed by outside organizations not using federal funds. Other excerpts are missing essential context that shows the statements actually describe permissible activities, such as providing technical assistance at the request of a policymaker.

At HHS, we are committed to fulfilling the mandates from Congress to empower communities to pursue high-quality, science-based programs that make a real difference in the health of Americans. The CTG awardees are working hard to reduce the impact of chronic diseases on our population and health system. We are committed to enabling their success and to ensuring that federal funds are used efficiently and appropriately. With this work in prevention we can save lives, better manage our health-care costs, and help Americans be more productive.

Stryene

Please provide a status and estimated timeline on the National Academy of Sciences review of the classifications of formaldehyde and stryene in the 12th Report on Carcinogens.

Answer: The Office of the Assistant Secretary for Health is proceeding with an acquisition to support the review of the determinations for formaldehyde and styrene in the 12th Report on Carcinogens. The contract will be awarded prior to September 30, 2012.

Tuberculosis

Tuberculosis is a significant global health concern and is the second leading cause of death from infectious disease worldwide. How much money has NIAID budgeted to help eradicate TB? Is HHS funding the late stage development of a TB vaccine? If so, how much money has been allocated to this research, and through what channels?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) is the lead for tuberculosis (TB) research, and is committed to conducting and supporting research focused on all aspects of TB, including drug-susceptible and drug-resistant TB, as well as TB in HIV co-infected persons. In FY 2013, NIAID funding for basic, translational, and clinical research to combat TB is estimated to be about $158 million. (Total NIH spending on TB research in FY 2013 is estimated to be $210 million.) NIAID-supported basic research provides the foundational knowledge that underlies clinical and translational research to develop new diagnostics, drugs, and vaccines for TB. For example, NIAID has supported basic, preclinical,

and clinical stages of development of approximately ten TB vaccine candidates that are currently in various stages of development.

In FY 2013, NIAID funding for TB vaccine research, including clinical trials, is estimated to be almost $15 million. In addition, NIAID currently supports collaborative clinical studies with Aeras, a Rockville, Maryland-based nonprofit organization focused on developing vaccines and other products to prevent TB. These studies are evaluating prophylactic TB vaccines, including a Phase II safety and efficacy trial of an adenovirus-based booster following administration of the current TB vaccine, BCG, to HIV-negative infants at birth. In addition, NIAID recently contributed critical animal model data for a novel vaccine candidate that shows promising results in animal models of TB. This vaccine candidate, now entering trials in humans, may result in a vaccine that could prevent activation of disease in individuals with latent TB who constitute a significant source of potential new cases of TB.

Continued Excessive Use of Special Title 42 Pay Authority
The Health and Human Services Department (HHS) has limited special authority under Title 42 to allow HHS certain hiring and pay flexibilities. The special authority was created in the 1930's to provide for limited scientific appointments and not as an alternative compensation scheme. The authority allows HHS to avoid some normal Civil Service hiring rules and provide employees with higher salaries, recruitment bonuses, and retention bonuses. The authority covers limited Senior Biomedical Researches, such as the 27 National Institutes of Health Directors, special consultants, and a category of employees HHS identifies as Administrative Determined employees.

I was surprised to see the continued over use of this authority. Moreover, I understand in December during another review the General Accountability Office (GAO) identified a violation of an appropriations restriction that impacts hundreds of these category of employees and creates an anti-deficiency (ADA) violation. Please provide a detail summary of the violation, timeline of expected ADA notification, plan to correct the issue, and citations to the appropriate authorities for each aspect of the question.

In the House 2012 Chairman's bill, we included a provision to limit the number of federal employees being paid in excess of Executive Level III. We understand, in HHS data demonstrates that almost 900 employees earned between $179,700 to $350,000 in base salary during FY 2010, far more than a grantee could earn in salary from a HHS grant in FY 2010.

We appreciate HHS may require some flexibility to compensate a handful of key scientists, certainly not in the hundreds, at slightly higher salary. It is hard to justify, especially in these tough economic times, why HHS compensates many of these in excess of what they would earn in the private sector. Public service certainly should provide a reasonable standard of living but not the top salaries in the field. Please identify the number of title 42

employees in FY 2012 that could be paid above executive level III if the 2012 House provision was enacted at 1 percent, 0.5 percent, and 0.25 percent.

In addition, please provide a table that displays at the HHS Operating Division, Office of the Secretary Offices, and total HHS for the following factors for each FY from FY 2007 through FY 2012:

- **Annual Total Number of FTE; Annual Total Number of FTE Employed Under Any Title 42 Authority; Annual Number of Title 42 FTE with an Annual Salary equal to or above the Executive Level III for that FY; Annual Number of Title 42 Employees who received a Retention Bonus; Annual Number of Title 42 Employees who Received a Recruitment Bonus; Annual Number of Title 42 Employees who Received Both a Recruitment and Retention Bonus; Annual Salary Cap; Annual Maximum Recruitment Bonus; and the Annual Maximum Retention Bonus; Annual Number of employees compensated under each applicable Title 42 authority (for example, Sections 209(f) and 209(g)); and**
  Annual Number of the Title 42 appointments indicating which ones were for new hires and which ones were conversions.

Answer: It has been recently discovered that term-limited Title 42 employees have been paid in excess of a cap on such payments and HHS has taken the necessary steps to ensure that all current appointments are consistent with the cap. HHS is investigating the matter, determining whether violations of the Anti-Deficiency Act have occurred, and, if such is the ultimate finding, will provide the appropriate notification.

The following tables provide information from the HHS Office of Human Resources' Business Intelligence Information Systems (BIIS), which included Capital HR (CapHR) data and the Defense Finance and Accounting Services (DFAS) payroll data for FY 2007 through FY 2011. This level of detail is not available for FY 2012.

OPDIV	2007	2008	2009	2010	2011
ACF					
Total FTE used	1,229	1,283	1,238	1,331	1,338
Total Title 42 FTE	-	-	-	-	-
Total # of Title 42 209 F staff	-	-	-	-	-
Total # of Title 42 209 G staff	-	-	-	-	-
Total # Title 42 Recruitment Bonus	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-
AHRQ					
Total FTE used	295	297	288	312	313
Total Title 42 FTE	52	47	43	31	12
Total # of Title 42 209 F staff	5	3	3	3	3
Total # of Title 42 209 G staff	48	35	32	25	11
Total # Title 42 Recruitment Bonus	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-
AoA					
Total FTE used	112	106	101	100	115
Total Title 42 FTE	-	-	-	-	-
Total # of Title 42 209 F staff (positions)	-	-	-	-	-
Total # of Title 42 209 G staff (positions)	-	-	-	-	-
Total # Title 42 Recruitment Bonus (positions)	-	-	-	-	-
Total # Title 42 Retention Bonus (positions)	-	-	-	-	-
CDC					
Total FTE used	8,569	8,944	9,567	10,179	10,672
Total Title 42 FTE	702	796	922	991	1,100
Total # of Title 42 209 F staff (positions)	94	97	105	104	105
Total # of Title 42 209 G staff (positions)	747	879	1,009	995	985
Total # Title 42 Recruitment Bonus (positions)	5	5	14	5	11
Total # Title 42 Retention Bonus (positions)	8	5	3	4	4

OPDIV	2007	2008	2009	2010	2011
CMS					
Total FTE used	4,526	4,483	4,381	4,537	5,165
Total Title 42 FTE	15	13	9	8	6
Total # of Title 42 209 F staff (positions)	-	-	-	-	-
Total # of Title 42 209 G staff (positions)	-	-	-	-	-
Total # Title 42 Recruitment Bonus (positions)	-	-	-	-	-
Total # Title 42 Retention Bonus (positions)	-	-	-	-	-
FDA					
Total FTE used	9,618	9,909	11,310	12,522	13,332
Total Title 42 FTE	533	551	795	870	858
Total # of Title 42 209 F staff (positions)	251	249	232	223	215
Total # of Title 42 209 G staff (positions)	394	496	698	800	783
Total # Title 42 Recruitment Bonus (positions)	1	65	55	5	-
Total # Title 42 Retention Bonus (positions)	114	95	120	18	26
HRSA					
Total FTE used	1,708	1,484	1,481	1,609	1,860
Total Title 42 FTE	3	3	4	4	4
Total # of Title 42 209 F staff (positions)	-	-	-	-	3
Total # of Title 42 209 G staff (positions)	-	-	-	-	2
Total # Title 42 Recruitment Bonus (positions)	-	-	-	-	1
Total # Title 42 Retention Bonus (positions)	-	-	-	-	1
IHS					
Total FTE used	15,062	14,985	15,267	15,830	15,485
Total Title 42 FTE	2	2	1	4	3
Total # of Title 42 209 F staff (positions)	-	-	-	-	-
Total # of Title 42 209 G staff (positions)	-	-	-	-	-
Total # Title 42 Recruitment Bonus (positions)	-	-	-	-	-
Total # Title 42 Retention Bonus (positions)	-	-	-	-	-
NIH					
Total FTE used	16,986	17,241	17,785	18,351	18,569
Total Title 42 FTE	4,234	4,348	4,537	4,766	4,792
Total # of Title 42 209 F staff (positions)	2,334	2,458	2,530	2,580	2,531
Total # of Title 42 209 G staff (positions)	2,432	2,541	2,609	2,729	2,846
Total # Title 42 Recruitment Bonus (positions)	59	72	62	53	32
Total # Title 42 Retention Bonus (positions)	75	68	55	26	16
OS (including PSC)					
Total FTE used	4,976	5,201	5,317	5,691	6,242
Total Title 42 FTE	11	11	11	11	12
Total # of Title 42 209 F staff (positions)	5	2	7	8	9
Total # of Title 42 209 G staff (positions)	3	4	1	5	7
Total # Title 42 Recruitment Bonus (positions)	-	-	-	1	1
Total # Title 42 Retention Bonus (positions)	-	-	-	-	-
SAMHSA					
Total FTE used	511	533	519	530	547
Total Title 42 FTE	10	11	7	6	-
Total # of Title 42 209 F staff (positions)	-	-	-	-	-
Total # of Title 42 209 G staff (positions)	-	-	-	-	-
Total # Title 42 Recruitment Bonus (positions)	-	-	-	-	-
Total # Title 42 Retention Bonus (positions)	-	-	-	-	-

Annual Number of Title 42 FTE with an Annual Salary equal or above the Executive Level III for the year	Fiscal Year				
	2007	2008	2009	2010	2011
ACF	-	-	-	-	-
AHRQ	5	4	4	4	6
AoA	-	-	-	-	-
CDC	99	90	89	91	91
CMS	-	-	-	-	-
FDA	70	89	94	105	103
HRSA	-	-	-	-	3
IHS	-	-	-	-	-
NIH	885	1,040	1,024	1,085	1,115
OS	5	3	8	9	9
PSC	-	-	-	-	-
SAMHSA	-	-	-	-	-

Annual Number of Title 42 Employees who received both a Recruitment and Retention Bonus	Fiscal Year				
	2007	2008	2009	2010	2011
ACF	-	-	-	-	-
AHRQ	-	-	-	-	-
AoA	-	-	-	-	-
CDC	-	-	-	-	-
CMS	-	-	-	-	-
FDA	-	-	-	-	-
HRSA	-	-	-	-	-
IHS	-	-	-	-	-
NIH*	1	-	-	-	-
OS	-	-	-	-	-
PSC	-	-	-	-	-
SAMHSA	-	-	-	-	-

**One individual incorrectly received both a recruitment and retention bonus in 2007 from NIH. NIH is taking corrective actions to address this.*

Annual Salary Cap	Fiscal Year				
	2007	2008	2009	2010	2011
ACF, AHRQ, AoA, CMS, HRSA, IHS, OS, PSC, SAMHSA	$250,000	$250,000	$250,000	$250,000	250,000
CDC, FDA, NIH*	$350,000	$350,000	$350,000	$350,000	350,000
**The NIH salary caps for staff in 209 F appointments is $350,000 and $200,000 for 209 G appointments.*					

Annual Maximum Recruitment Bonus	Fiscal Year				
	2007	2008	2009	2010	2011
ACF	-	-	-	-	-
AHRQ	-	-	-	-	-
AoA	-	-	-	-	-
CDC	$67,500	$35,089	$37,400	$53,750	$53,359
CMS	-	-	-	-	-
FDA	$19,800	$33,750	$20,492	$40,000	-
HRSA	-	-	-	-	$22,375
IHS	-	-	-	-	-
NIH	51,250	$57,250	$50,000	45,000	$62,500
OS	-	-	-	$20,097	$25,000
PSC	-	-	-	-	-
SAMHSA	-	-	-	-	-

Annual Maximum Retention Bonus	Fiscal Year				
	2007	2008	2009	2010	2011
ACF	-	-	-	-	-
AHRQ	-	-	-	-	-
AoA	-	-	-	-	-
CDC	$46,602	$38,196	$25,877	$20,973	$25,367
CMS	-	-	-	-	-
FDA	$32,608	$17,980	$26,492	$14,606	$13,630
HRSA	-	-	-	-	$4,975
IHS	-	-	-	-	-
NIH	$49,831	$68,999	$44,681	$45,001	$45,845
OS	-	-	-	-	-
PSC	-	-	-	-	-
SAMHSA	-	-	-	-	-

Annual Number of Title 42 Hires (positions)	Fiscal Year				
	2007	2008	2009	2010	2011
ACF	-	-	-	-	-
AHRQ	5	2	3	4	1
AoA	-	-	-	-	-
CDC	169	192	183	198	179
CMS	-	-	-	-	-
FDA	197	178	322	165	168
HRSA	-	-	-	4	2
IHS	-	-	-	-	-
NIH	650	699	667	648	575
OS	1	1	5	3	5
PSC	-	-	-	-	-
SAMHSA	-	-	-	-	-

Annual Number of Title 42 Conversions (Positions)	Fiscal Year				
	2007	2008	2009	2010	2011
ACF	-	-	-	-	-
AHRQ	14	11	12	2	5
AoA	-	-	-	-	-
CDC	142	145	182	142	164
CMS	-	-	-	-	-
FDA	94	214	151	187	167
HRSA	-	-	-	-	-
IHS	-	-	-	-	-
NIH	513	694	581	463	489
OS	-	-	-	-	-
PSC	-	-	-	-	-
SAMHSA	2	-	-	-	-

We understand the intent of the Chairman's FY 2012 provision referenced in your question was to address those hired under sections 209(f) and 209(g) of Title 42 and to include employees at FDA and IHS but not the Environmental Protection Agency. Had the provision been enacted following these assumptions, the below table reflects the number of employees who could be paid at levels above Executive Level III at each of the caps you requested based on FY 2011 data. At each level, this would be a significant reduction in pay for some of our brightest scientific minds and hinder recruitment of experts in the health field.

Title 42 F & G	Total Title 42 Positions
Total Title 42 209 F & G Employees end of FY 2011	7,500
Above Exec Level III at 1%	75
Above Exec Level III at 0.5%	38
Above Exec Level III at 0.25%	19

Discretionary Abstinence Education (AE) Program

Please explain why the request proposes to eliminate the Abstinence Education (AE) program funded in the Office of the Secretary. We understand that no less than 22 studies show AE is effective for teens regardless of their prior sexual experience.

Answer: HHS has made many difficult funding decisions for FY 2013. As such, HHS feels that its request to not fund an Abstinence Education Program in the Office of the Secretary (OS) will have a minimal effect on the overall abstinence education programs in the Department. Specifically, the Administration for Children and Families' (ACF) portfolio includes $50 million in Abstinence Education as well as supporting $75 million for the Personal Responsibility Education Program (PREP) which focuses on educating youth on both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, including HIV/AIDS.

Within the OS, the Teen Pregnancy Prevention (TPP) program provides $105 million to support community-based programs that have been proven effective through a systematic, comprehensive review of rigorously evaluated program models aimed at preventing teen pregnancy, STIs, and sexual risk behaviors. The evidence review was conducted by Mathematica Policy Research, Inc. (Mathematica) under a contract with HHS and managed by the Assistant Secretary for Planning and Evaluation (ASPE) in collaboration with the Office of Adolescent Health (OAH) and ACF. The initial evidence review in 2010 produced a list of 28 evidence-based program models for youth. The program models include a range of approaches to serve youth, including youth development, sex education, abstinence education, and clinic-based programs. Two abstinence education program models were identified by grantees and are currently being replicated by 9 separate grantees. The models being replicated are: PHAT (Promoting Health Among Teens) Abstinence Only Intervention and Making a Difference.

Title V Abstinence Education Program

Your budget proposes to redistribute funds that remain unused by some states under the title V abstinence education program to other Departmental programs which are not focused on abstinence education. Please cite the specific legal authority that allows HHS to repurpose these title V AE funds for non-AE programs?

Answer: The FY 2013 President's Budget is requesting authority for the Department of Health and Human Services to repurpose unused, mandatory Abstinence Education funds for a new, discretionary pregnancy prevention program for foster care youth. Historically, approximately $12-$15 million goes unobligated because some states do not request available funds for abstinence education.

Independent Payment Advisory Board (IPAB)

IPAB's enacting legislation says it can't ration care or restrict benefits. I understand an American Medical Association survey indicates the current reimbursement rates have already led to 17 percent of all doctors, including 31 percent of primary care physicians, to restrict the number of Medicare patients in their practices. It seems IPAB could have a

negative impact on access to physician care for Medicare. If IPAB recommends rate cuts, how will HHS propose to ensure Medicare providers do not reduce slots or ration care?

Answer: The AMA Online Survey cited above indicates that the large majority of physicians *do not* restrict the number of Medicare patients in their practice. Additionally, reports by MedPAC and GAO indicate access to care for Medicare beneficiaries remains strong. Analysis recently published by the Medicare Payment Advisory Commission (MedPAC, March 2012) shows that the supply of physicians and other health professionals billing Medicare has grown and surveys show high acceptance of Medicare patients. Both participation and assignment rates have grown significantly since 1990 and remain at very high levels. Among office-based physicians with at least 10 percent of revenue from Medicare, more were willing to accept new Medicare patients than were willing to accept new private insurance patients, and MedPAC's 2011 telephone survey of Medicare patients found that overall access to care is good. The Government Accountability Office also concluded that Medicare beneficiaries had stable access to physician services and experienced few problems accessing physician services.

As specified in ACA, IPAB must, to the extent feasible, give priority to recommendations that improve health outcomes and protect Medicare beneficiaries' access to necessary care. CMS will continue to monitor participation levels and other indicators of access to care to ensure Medicare beneficiaries have access to the care they need.

The IPAB's enacting legislation says the Board should focus on recommendations to improve quality of care, but does not mandate quality of care goals-- only spending cut goals. Please explain what mechanisms are in-place or planned to ensure the mandate that savings must be achieved in a short one-year time frame will not drive the Board to make annual provider payment cuts?

Answer: IPAB is required by law to make recommendations that would reduce excess cost growth in Medicare while also focusing, to the extent feasible, on improving health outcomes and protecting Medicare beneficiaries' access to necessary care. IPAB can propose a mix of recommendations that have both near-term and longer-term effects on the payment and delivery of care to Medicare beneficiaries. IPAB is also instructed to consider the effects of its recommendations on providers of services and suppliers and target reductions in Medicare program spending to sources of excess cost growth. IPAB members will provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representation. Moreover, Congress can enact alternative measures to strengthen the Medicare program in lieu of IPAB's recommendations.

Preparedness and Response
We understand the Administration's desire is to combine activities to promote better coordination between preparedness and response activities. Please explain how this consolidation will impact funding for preparedness programs? Please explain what criteria was used to determine the nation's preparedness level in the 2013 request, which reduces funding for core public health security programs such as Public Health Emergency Preparedness at CDC? How does the request ensure gains made with the federal investments in the Public Health Preparedness Cooperative Agreements and the Hospital

Preparedness Program is maintained? Please explain the rationale for the Hospital Preparedness Program reduction of $125 million in FY 2013?

Answer: Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. Initially, this funding was to support grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

The Administration is committed to cutting the deficit, restoring fiscal sustainability, and achieving better performance with the resources we have. The Budget proposes a 33 percent reduction to HPP. In addition, current efforts to align preparedness grants to improve effectiveness may lead to administrative efficiencies and reduce costs to the programs. In FY 2012, the first joint funding opportunity announcement was issued for the PHEP and HPP programs; the streamlining of these grants will reduce the administrative burden and will accrue savings to the program at both the Federal and grantee levels. By enhancing cohesion between the preparedness programs, states will also be able to make more efficient use of the resources, which is imperative in a constrained budget environment.

Presently, the Department's preparedness and response activity are managed and funded separately but maintain a high degree of coordination between the two, which is vital to an effective response. The Department utilizes a variety of training exercises and working groups to ensure that preparedness planners and those engaged in disaster response share information and best practices to continuously improve our Nation's capabilities in support of all-hazards preparedness. The Department is also engaging across the healthcare spectrum of State and local actors to work with emergency medical response services, public health departments, behavior health experts, and hospitals in supporting healthcare coalitions which are ready for whole community disaster response. Viewing preparedness and response efforts under this paradigm not only enhances our Nation's response capabilities and resiliency, but also supports more effective and efficient exchange of information during a disaster.

Medicare Contractors
Please explain to the Subcommittee the role that Medicare Contractors play in the Medicare program and how their authority relates to various state authorities governing medical practices within each state?

Answer: CMS is responsible for the administration of the fee-for-service (FFS) Medicare program and by statutory requirement, does so primarily through contractors. As Medicare's agents, these contractors are responsible for executing the daily operational aspects of Traditional Medicare by processing claims and performing other business related functions that support the regular daily interactions with Medicare FFS providers. Our Medicare FFS contractors are responsible for the day-to-day oversight and administration of the Medicare FFS program, including: provider enrollment, determination of payment amounts, making payments, provider consultative services (e.g., on maintaining fiscal records), communication with providers, provider education and technical assistance, and additional necessary administrative

functions such as auditing and program integrity activities. We also use State surveyors to perform Survey and Certification activities in the States, and contract with private health insurers to provide to Medicare beneficiaries through Medicare Advantage (Part C) and the prescription drug benefit program (Part D). In addition, CMS uses contractors to respond to beneficiary inquiries through 1-800-MEDICARE.

Preventive Health and Health Services Block Grant
Please explain the projected impact on the state and local public health protection with the proposed elimination of the CDC Prevention Block Grant?

Answer: Through CDC's existing and expanding activities, there is substantial funding to state health departments to address community health needs. The activities currently supported by the Preventive Health and Health Services Block Grant may be more effectively and efficiently implemented through the new Coordinated Chronic Disease Prevention and Health Promotion Grant. The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

Chronic Disease Coordination
Again the President's FY 2013 request proposes to consolidation existing CDC chronic disease programs into a single program. Please specifically identify all the efficiencies CDC expects to gain from this proposal? Plus, describe the specific policy and metrics that would ber put in place to provide to ensure the specific disease areas being consolidated are reasonably supported? The request does not include any bill language to provide this assurance to support the specific diseases, please provide such language for Congressional coordination.

Answer: The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful

behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services.

The efficiencies achieved from a consolidated approach to chronic-disease prevention programming will:

- Allow all states to receive funding to support core chronic disease prevention and health promotion functions while increasing the opportunity to invest a greater share in program activities;
- Provide states with the flexibility to focus a greater share of program implementation funding on addressing the aggregate chronic disease burden in their respective state;
- Offer states greater flexibility to organize health departments and programs without the fiscal and programmatic limitations currently placed on the individual funding streams;
- Allow states to focus on health outcomes and public health impact rather than tracking multiple funding sources for each chronic disease separately; and
- Consolidate funding, providing CDC with the opportunity to expand its reach to address chronic diseases with the full complement of targeted programs.

CDC will track overarching contextual indicators of chronic disease-related deaths and has identified proximal performance measures that identify the short term and intermediate outcomes and the impact of programmatic efforts to reduce chronic diseases and contributing risk factors. These overarching contextual indicators include:

- Reduce the age-adjusted annual rate of coronary heart disease deaths per 100,000 population from 122.7 in FY 2008 to 108.6 in FY 2015.
- Reduce the age-adjusted annual rate of stroke deaths per 100,000 population from 40.7 in FY 2008 to 36.4 in FY 2015.
- Reduce the age-adjusted annual rate of diabetes-related deaths per 100,000 population from 73.1 in FY 2007 to 68.5 in FY 2015.

CDC would work very closely with states in reviewing state plans to ensure the specific disease areas being consolidated are reasonably supported. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes. These goals can be adequately accomplished with CDC's existing authorities and do not need to be supplemented by additional bill language.

Glaucoma

Dr. Frieden, in fiscal year 2012, $3.3 million was appropriated for the glaucoma program. We understand that in the next few months, the CDC will be publishing an RFP for a competition for these funds. While we fully support the competition, we have several concerns:

- **We understand that the RFP may award as many as three grants. If this is the case, providing smaller grant awards would provide insufficient funds to operate quality glaucoma programs, greatly reducing the number of screenings and resulting in delayed treatment and lose of sight.**

Answer: The CDC aims to develop an effective glaucoma program that will design, implement and evaluate a glaucoma screening program with the intent of capturing best practices that will be shared widely for the benefit of expanding the reach and effectiveness of glaucoma screening programs in the US.

The funding opportunity announcement (FOA), "Improving Access to Eye Care among Persons at High Risk for Glaucoma" was released on March 27, 2012. Through this program, CDC will fund up to two awards to improve glaucoma screening, referral, and treatment for those populations experiencing the greatest disparity in access to glaucoma care—Hispanics, blacks, Asians, older people (aged 60 years and older), those with a family history of glaucoma, and those with diabetes—by implementing community-based outreach programs. By funding up to two awards, CDC anticipates:

a) Expanding the reach of the program
b) Targeting diverse populations in different communities
c) Broadening the variety of approaches and strategies available to effectively implement glaucoma screening programs to reach populations at high risk of developing glaucoma.

- **The second concern is the eligibility requirements in the RFP. Given your chronic disease consolidation proposal in the fiscal year 2013 budget, I am concerned that state health departments may be the only entities eligible for these funds.**

- **What other entities, other than State departments of health be eligible to compete?**

- **The fiscal year 2013 budget proposes to consolidate several programs, including the glaucoma screening program, into a new Coordinated Chronic Disease Prevention and Health Promotion Program. States could use funds from this program on a broad range of chronic diseases.**

Answer: The new funding opportunity announcement, "Improving Access to Eye Care among Persons at High Risk for Glaucoma" is an open competition announcement and the eligibility criteria extend beyond states. As stated in the FOA, eligible applicants that can apply for the funding opportunity include:

• Nonprofit organizations with IRS status (other than institution of higher education);
• Nonprofit organizations without IRS status (other than institution of higher education);
• For-profit organizations (other than small business), small, minority, and women-owned businesses, universities, colleges, research institutions, hospitals, community-based organizations, faith-based organizations;
• Federally recognized or state-recognized American Indian/Alaska Native tribal governments, American Indian/Alaska native tribally designated organizations, Alaska Native health corporations, Urban Indian health organizations, Tribal epidemiology centers, and;
• State and local governments (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), Political subdivisions of States (in consultation with States)

The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

- **Would this new Coordinated Chronic Disease program give guidelines to States to cover certain chronic diseases, such as glaucoma screening?**

Answer: The Coordinated Chronic Disease Prevention and Health Promotion Program will support four priority areas: 1) evidence –based practice and environmental approaches to improve nutrition and physical activity in schools, worksites, and communities 2) health system interventions to improve the delivery and use of selected clinical and other preventive services in order to prevent disease, detect diseases early and manage risk factors; 3) strategies to improve community-clinical linkages to support chronic disease self-management and 4) epidemiology and surveillance. Glaucoma screening represents an activity that states could potentially pursue as part of priority areas two and three, or that national organizations could pursue as part of the coordinated program.

- **Do States currently have the capacity and equipment to do glaucoma screenings?**

Answer: Findings from the 2005 report, "*Vision Problems in the United States: Recommendations for a State Public Health Response*" conducted by the National Association of Chronic Disease Directors and CDC suggest states have limited capacity to address glaucoma and other vision problems at the time the study was conducted.

- **How would States target glaucoma screenings for high-risk populations such as African- Americans and Hispanics?**

Answer: The glaucoma funding opportunity announcement (FOA) "*Improving Access to Eye Care among Persons at High Risk for Glaucoma*" is intended to improve glaucoma screening, referral, and treatment for populations experiencing the greatest disparity in access to glaucoma care—African Americans, Hispanics, older people (aged 60 years and older), those with a family history of glaucoma, and those with diabetes—by implementing community-based outreach programs. The work conducted through the glaucoma program and evaluation of the program's activities will provide valuable strategies, lessons and best practices to enhance the promotion of vision health.

Global Health Leadership
Dr. Frieden – in the March 3rd edition of Lancet, international writers were commenting on the apparent lack of focus of the CDC and its Center for Global Health Leadership. In the article entitled "Is CDC a science-based organization", they raise allegations and questions about CDC's "leadership, management of resources, proper use of the CDC's authority and power, and the scientific rigor of CDC research".

- **Why is the international public health community concerned about the CDC's commitment to the Global Health Initiative given the budgetary support Congress has provided?**

Answer: Two recently published "Comments" were penned by the Editor of the Lancet. His Op-Ed commentary is based on a couple of anonymous communications that raise questions about CDC leadership and scientific rigor. In response to the questions raised, the Lancet published a response from the CDC Director, Dr. Thomas Frieden, and the Director of the Center for Global Health (CGH), Dr. Kevin De Cock, on March 17th.

The strategy of the recently established Center for Global Health (CGH) at CDC is to enhance the public health capacity of global partners, increase global health security, and maximize the health impact of specific programs and interventions through a focus on scientific rigor, scalability, and sustainability.

CGH builds on CDC's 60-year history of evidence-based global health programs. Previously, CDC had five large and many small programs engaged in global health work; CGH was formed 2 years ago to draw together the large and coordinate the small programs to enable more effective collaboration within CDC and with host country, bilateral, and multilateral partners.

Since 2010, CDC has protected the health security of the U.S. by conducting nearly 500 outbreak and emergency response activities in 74 countries. CDC has contributed to substantial reductions in global childhood deaths (more than 50% in the past 30 years). CDC's AIDS work has contributed to significant declines in HIV incidence, and CDC has assisted countries such as India to make significant advances in polio eradication.

CDC's greatest strength is the staff's scientific rigor, programmatic expertise, and deep commitment to health and social justice. The establishment of CGH will, over the next 5 years, further strengthen public health infrastructure and capacity in low-income and middle-income countries; improve timeliness and effectiveness of responses to new and emerging health threats; and increase measurable effectiveness and efficiency of programs addressing infectious and non-communicable diseases for a fairer and healthier world.

As one of the Global Health Initiative (GHI) lead agencies, CDC is also committed to the Quadrennial Diplomacy and Development Review goals of strengthening the USG development response through a "Whole of Government" approach and the GHI principles and disease targets. We are working to reach the targets through improved activities, greater coordination and integration, and gains in efficiency.

- **Given these questions about the focus of the agency, your focus on the sodium and health issue is difficult to understand at a time when over the past several years numerous reports have challenged the feasibility, efficacy and safety of this public health policy. Can you explain the basis for your continued emphasis on this policy?**

Answer: These studies do not refute the long-standing and continuously growing collective body of consistent evidence indicating a positive effect of salt reduction on lowering blood pressure. Cardiovascular diseases are the leading cause of death worldwide and hypertension is a major contributor to cardiovascular diseases. Most of the sodium we eat comes from processed foods and foods prepared in restaurants. As evidenced by the range of sodium that can be found in many food types (e.g., a slice of white bread can range from 80 to 230 mg sodium per slice), sodium reduction is feasible. This position is further supported by corporate commitments to reduce sodium in their products. It has been estimated that reducing average sodium intake to 2,300 mg/day in the United States could potentially prevent 11 million cases of hypertension and save billions of dollars in health care expenditures.

In addition to the sodium-reduction goals included in *Dietary Guidelines for Americans, Healthy People 2020,* numerous professional health organizations, including the American Heart Association, the American Medical Association, and the American Public Health Association, support dietary sodium reduction as an effective strategy to prevent and control high blood pressure because of the weight of evidence demonstrating that excess sodium has a significant impact on high blood pressure.

CDC will continue to work with other federal agencies to monitor and assess the scientific evidence related to sodium reduction.

- **On the topic of scientific rigor, on July 11th, CDC colleagues of yours published a re-analysis of data from NHANES III in the *Archives of Internal Medicine.* In that article and in press releases from your office you claimed that higher sodium intake was associated with an increased risk of death. I understand that tables not in the article nor commented on by your CDC colleagues, but which the editors requested be posted electronically, it was evident the NHANES III database also identified a substantial increase risk of death in subjects eating less sodium. Please explain how your colleagues and CDC overlooked something so fundamental?**

Answer: According to the study published by CDC authors on July 11th in the Archives of Internal Medicine using the NHANES III data, a higher sodium intake was associated with higher mortality from all-causes, a higher potassium intake was associated with lower mortality risk from all-causes, and a higher sodium-to-potassium ratio was associated with higher mortality from both all-causes and cardiovascular diseases (CVD). The main findings of the study suggested that it is important to examine the sodium-to-potassium ratio because sodium and potassium have opposite effects on the pathogenesis of hypertension.

CDC authors posted all stratified analyses as the online supplemental tables. The results in the supplemental tables were generally consistent with the primary findings, as associations of increased sodium intake and sodium-to-potassium ratios with increased all-cause mortality were

consistent across different subgroups. Some of the risk ratios presented in the supplemental analyses for the relationship between *sodium* and *CVD-related death* were in the opposite direction from the main analyses. However, those analyses were based on smaller numbers of cases and their confidence margins did not reach statistical significance. When a finding does not reach statistical significance, it is generally accepted that the finding may not be real or may be due to chance. It is common to see this level of statistically non-significant variation in observational studies when examining sub-groups (race-ethnicity, gender, obesity, and hypertension status), and this variation does not negate the primary findings of the study.

Thus, the authors concluded in their response to the editor that: "We agree that any dietary recommendation including sodium reduction should not be based on the results from a single study. However, we believe that the weight of evidence from clinical trials and epidemiologic studies supports the current public health recommendations to reduce sodium intake, most of which comes from processed foods. Our study also provides evidence that increasing potassium intake while reducing sodium intake may confer additional health benefits."

Environmental Health/Lead

The Committee understood $350,000,000 will be spent by HHS to conduct home visiting programs in fiscal year 2012 through the Maternal, Infant, and Early Childhood Home Visiting Program.

- **Please explain what specific steps HHS will take in FY 2012 to encourage the HRSA and CDC to collaboratively ensure activities previously funded through Healthy Homes are fully incorporated into the Home Visiting Program?**

Answer: CDC and HRSA are working to identify possible solutions for integrating childhood lead poisoning prevention activities into routine services of HRSA's early childhood Home Visiting Program.

- **The FY 2013 request proposes to eliminate the Healthy Homes and Lead Poisoning Prevention Program. Please explain how the Administration would ensure children are tested for lead poisoning and how follow-up on the positive tests would be addressed?**

Answer: The FY 2013 Budget proposes a new program—Healthy Home and Community Environments—that will incorporate the National Asthma Control Program (NACP) and the Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The FY 2013 request for the Healthy Homes and Community Environments program is $27.3 million.

The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors.

Section 317

- **Please provide the specific assumptions and criteria used to support the proposed reduction to the 317 immunization program?**

Answer: The FY 2013 Budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The Budget does not continue funding for one-time enhancements planned for FY 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan. Health reform expansion will further increase access to immunizations and decrease the number of uninsured and underinsured individuals served by the Section 317 Program, resulting in cost savings.

- **Please describe how the requested FY 2013 level will be allocated to infrastructure and vaccines; in addition show the comparable breakout for FY 2011 and FY 2012.**

Answer: The allocation of Immunization funding towards vaccine purchase and immunization infrastructure is based on program needs and priorities. In FY 2011, approximately 45% was provided for vaccine purchase and 55% was targeted towards immunization infrastructure.

- **Please describe the rationale for cutting this program by $58 million or close to 10% and allocation of the cut to purchase grants?**

Answer: The FY 2013 Budget includes funds for vaccine purchase to continue outreach to the hardest to serve populations, and critical immunization operations and infrastructure that supports national, state, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs $25 million towards continuation of the billables project, which allows public health departments to vaccinate and bill for fully-insured individuals in order to maintain Section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The FY 2013 Budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The Budget does not continue funding for one-time enhancements planned for FY 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan.

- **Describe the How do you see the role of the 317 program evolving along with implementation of the Affordable Care Act?**

Answer: The Affordable Care Act requires new health plans to cover routinely-recommended vaccines without cost-sharing when provided by an in-network provider. As these health insurance reforms expand prevention services to more Americans, the size of the population currently served by Section 317 vaccine is expected to decrease in size, specifically underinsured

children. The Section 317 Immunization Program will continue to have a critical role in 1) providing vaccines to meet the needs of uninsured adults and responding to urgent vaccine needs such as outbreak response, and 2) ensuring the necessary infrastructure is in place to support the nation's immunization system for both routine vaccination as well as managing vaccine shortages and other emergency response. This critical infrastructure serves both the public (e.g., Vaccines For Children Program and Section 317) and private sectors. Insurance coverage alone will not provide the immunization infrastructure necessary to ensure a strong evidence base for national vaccine programs and policy, quality assurance for immunization services, and high vaccination coverage rates across the lifespan.

- **Please explain the criteria to determine the level of funding from the Prevention and Public Health Fund in FY 2012 and FY 2013 for the 317 immunization program.**

Answer: In FY 2012, the Prevention and Public Health Fund (PPHF) in part supported one-time infrastructure enhancements in health IT, planning and implementation of public health billing systems, adult vaccination, and capacity for vaccinating school-age children to help prepare the immunization program for the full implementation of the ACA. The FY 2013 PPHF funding level is based on the program's need to sustain its core vaccine purchase and infrastructure activities.

- **The Advisory Committee on Immunization Practices, under the direction of Dr. Frieden, has increasingly emphasized cost effectiveness in its decision-making process. How was this policy incorporated into Administration FY 2013 request allocation decisions process to distribute resources?**

Answer: There has been no policy change in the way that ACIP uses economic information in its decision-making processes. The ACIP reviews many factors when considering potential vaccine recommendations, including disease burden, safety, efficacy, effectiveness, and economic data including cost-effectiveness studies. While cost-effectiveness study results are reviewed at committee meetings, members are instructed not to make decisions based on budgetary concerns but rather to focus on the public health value of the recommendation. This has been a consistent policy throughout ACIP's history and does not impact the budget request allocation process.

CER Questions

1) HHS' FY 2013 budget proposal includes $62 million that the Agency for Healthcare Research and Quality will receive from the health reform law's CER Trust Fund for research "dissemination." It sounds a lot like AHRQ's ongoing project to "disseminate" CER findings under a so-called "academic detailing" program, where your agency sends government contractors into physicians' offices to make "practice change recommendations." Is the AHRQ-funded "National Resource Center for Academic Detailing" accurate when it says each visit "ends with specific practice-change recommendations."? Please explain what this means, the intent, and practical implications of these recommendations?

Answer: Beginning in FY 2011, a total of 20 percent of the funds appropriated or credited to the Patient-Centered Outcomes Research Trust Fund (PCORTF) are transferred each year to

HHS. These funds are distributed to the Secretary of HHS and the Agency for Healthcare Research and Quality (AHRQ). As authorized in section 937 of the Public Health Service Act, AHRQ is charged with using the funds it receives to establish grants to train researchers, disseminate research findings of the Patient Centered Outcomes Research Institute and other government-funded research, assist with the incorporation of research findings, and establish a process for receiving feedback on the information disseminated.

The dissemination projects funded with the PCORTF dollars are chosen to complement existing, ongoing efforts to disseminate research results from AHRQ's Effective Health Care program. The projects funded with the PCORTF funding include a wide range of projects intended to disseminate research findings to broad audiences, build awareness overall about patient-centered outcomes research, establish partnerships with national and local organizations, and support continuing medical and health professional education.
The National Resource Center for Academic Detailing (NaRCAD) is an AHRQ-funded Recovery Act grant project conducted by the original pioneers of "academic detailing" at the Brigham and Women's Hospital. The NaRCAD project is developing a national resource center to adapt AHRQ's comparative effectiveness research products for use in these one-on-one educational visits and to train clinician-educators in methods to disseminate this information in a wide variety of practice settings.

These projects all have one goal: to provide information that clinicians and patients can use in making the best treatment decisions possible based on patients' individual situations. These activities are intended to encourage greater use of evidence in health care decision-making, not to direct clinicians' behavior or to dictate a particular type of treatment.

2) Please explain the criteria and specific projects that AHRQ has fund with funds from the CER Trust Fund? We understand AHRQ officials have developed a draft spending plan for these funds to HHS and the PCORI Board. To promote government transparency, why are these plan not put in the AHRQ and HHS public web site? Please provide a copy of each for the record.

Answer: The FY 2011 AHRQ Patient-Centered Outcomes Research Trust Fund (PCORTF) spend plan was developed in accordance with the authorizing legislation for the Patient-Centered Outcomes Institute (PCORI). Specifically, the projects are intended to "create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers" and "build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials." Projects included in both spend plans were chosen to be consistent and complementary with PCORI activities and needs. This was accomplished via the presence of AHRQ and NIH senior leaders as members of the PCORI Board of Governors and Methodology Committee. Additionally, AHRQ and NIH have regular consultations regarding patient-centered outcomes research and PCORI that has ensured that activities in the spend plan are unique and not duplicative. Finally, AHRQ is frequently collaborating with HHS Office of the Secretary on these activities and this has also served to make sure the projects below are complementary of OS activities.

The FY 2011 AHRQ PCORTF spend plan was summarized in the FY 2013 Congressional Justification, located here: http://www.ahrq.gov/about/cj2013/cjweb13.htm.

3) A recent article in Forbes identified some of the interesting projects that HHS is funding using Recovery Act CER funding. These included a study to "inform public policy" about whether use of feeding tubes in patients with dementia could be reduced as a way to cut health costs. The article also identified a project with the Corporation for Public Broadcasting and the Hastings Center on end-of-life care and other bioethical issues. What is the status of these projects – are they ongoing?

Answer: The study of the use of feeding tubes in individuals with advanced cognitive impairment is ongoing. Eating difficulties are common among individuals with advanced or late-stage dementia, and these patients can be treated with the insertion of a feeding tube directly into the stomach (percutaneous endoscopic gastrostomy, or PEG). Usual or standard care for difficulty swallowing or eating for these patients includes hand feeding or insertion of a naso-gastric feeding tube. PEG tube feeding offers some advantages, but the PEG tube requires surgical insertion, with some attendant risks; in addition, patients who are fed via PEG tube remain at risk for being treated with restraints and powerful sedatives (to prevent them from removing the tube) and for being transferred to an emergency room or acute care facility – which itself can be burdensome to the patient and his or her family and is associated with fragmentation of care, changes in the management of chronic conditions, duplication of diagnostic workups, and medical errors, as detailed in a recent NIH-supported study in the *New England Journal of Medicine*. The effect of PEG tube feedings on overall survival among these individuals is unclear. In addition, PEG tube usage varies widely among states, referral regions, and hospitals. In this study, NIH-supported investigators are using large data sets to explore the risks and benefits of PEG insertion in patients with advanced dementia and to identify hospital characteristics and state policies that could account for variation feeding tube insertion rates. Recently, the investigators reported in the *Journal of the American Medical Association* that among nursing home residents with advanced cognitive impairment admitted to acute care hospitals, for-profit ownership, larger hospital size, and greater ICU use were associated with increased rates of feeding tube insertion. Our ultimate goal is to ensure that PEG tube insertion in patients with advanced cognitive impairment is consistent with the best available data on their effectiveness. To the extent that cost is explored in this study, the ultimate goal is to reduce the use of unwanted, potentially harmful, and expensive procedures that are being conducted on people who are not able to speak for themselves.

The NIH grant to the WGBH Educational Foundation (and the Hastings Center) resulted in the production of a film entitled "Cracking Your Genetic Code," which aired on PBS on March 28, 2012. The show explores some of the issues that will likely arise once the process of sequencing individual genomes becomes affordable for everyone. The show looks at the moral dilemmas of knowing which diseases may lay in someone's future and what happens if that information falls into the hands of insurance companies, employers, or prospective mates. This new era of personalized, gene-based medicine is relevant to everyone.

Although this project did not receive funds from the National Human Genome Research Institute Ethical, Legal and Social Implications (ELSI) Research Program, "Cracking Your Genetic Code" does support ELSI's statutory mission to foster the understanding of the "ethical, legal and social implications of genetic and genomic research for individuals, families and communities." With the completion and airing of the film, the project is complete and the grant is in the process of being closed out, with a project end date of 08/31/2012.

4) Dr. Joe Selby, the head of the new comparative effectiveness research institute set up under health reform, was also on an Institute of Medicine Committee that made recommendations to HHS last year on essential health benefits. I understand, this IOM committee recommended HHS make coverage decisions for the EHB benefits package using a cost-effectiveness threshold. In addition, Dr. Selby released a draft research agenda for the new CER institute that includes cost. HHS has two people on PCORI's board, do you and the HHS board members share his views that PCORI should include cost in its research agenda, and that HHS should use PCORI research to make EHB coverage decisions based on comparative and cost-effectiveness?

Answer: The language in the statute (P.L. 111-148, §6301(c)) is clear about the role of costs in PCORI research, stating that PCORI "shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended". Similarly, the statute also states that "the Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs...". Regarding HHS use of the research findings from PCORI, the statute (P.L. 111-148, §6301(a)) states, "[n]othing in this section shall be construed to permit the Institute to mandate coverage, reimbursement, or other policies for a public or private payer...".

Drs. Carolyn Clancy and Francis Collins sit on the Board of Governors as the heads of AHRQ and NIH, as stipulated in statute, and both have reinforced the legislative intent. PCORI's draft research agenda was recently made available for public comment and, it is my understanding, that the public comments will be reflected in the next iteration of the research priorities that the Board will consider. HHS has always advocated for the use of research findings for making health care decisions and the use of research findings helps to make sure that decisions are not made that could harm patients. Above all, research findings on the benefits and safety risks of different health care services or interventions should inform decisions so that Americans can receive the highest quality and safest care possible.

Questions For the Record,
From Rep. Mike Simpson

- **A year ago at this time I was very concerned about the decision to downgrade the Division of Oral Health at the CDC. I appreciate the decision to reverse that move. It reconfirmed to the dental community that oral health is a top priority of your department.**

Last December there were 4 chief dental officer positions (CMS, CDC, IHS and HRSA) in your department that were either vacant or filled with acting directors. I am please you have filled the CMS vacancy. The IHS and CDC have had acting directors for more than year. When will you begin searching for permanent directors?

Answer: Currently CDC is conducting a national search for a permanent Division Director for the Division of Oral Health. CDC expects to select an individual by mid-summer 2012. In the interim Dr. William Bailey, current USPHS Chief Dental Officer, will remain as the Acting Division Director for the Division for Oral Health.

IHS has not yet posted an advertisement to permanently fill the Division of Oral Health Director position; however, it is a priority position to be filled as soon as possible in 2012.

- **I understand that the HRSA Chief Dental Officer was filled earlier this year. However, the position was downgraded to "advisor." (HRSA Senior Advisor for Oral Health) Why is that?**

  Such a move sends another message to the dental world that oral health isn't as important as medical. Can you do something about restoring the "advisor" to chief dental officer status equal to the medical officer?

Answer: Currently CAPT Renee Joskow serves as HRSA's Senior Dental Advisor and is responsible for coordinating oral health activities across all HRSA programs, advises program officials throughout HRSA on the recruitment, assignment, deployment, retention, and career development of dentists and other oral health professionals within the agency. The Senior Advisor position encompasses the same reporting level and duties of the Chief Dental Officer. "Senior Advisor" is a more contemporary term used by the HRSA to identify an individual who has the lead, within the Agency, or within a Bureau, for a particular content area and provides input to the organization's leadership.

- **Lately those who oppose community water fluoridation have been using the social network to air information casting doubt on the benefits of fluoride. What would be helpful is if the Surgeon General would issue a statement in support of fluoridation. Can we get a statement from the Surgeon General addressing the benefits of fluoridation?**

Answer: The Department, in partnership with the Environmental Protection Agency, released a statement in January of 2011 announcing important steps to ensure that standards and guidelines on fluoride in drinking water continue to provide the maximum protection to the American people to support good dental health, especially in children. Specifically, HHS proposed that recommended level of fluoride in drinking water be set at the lowest end of the current optimal range to prevent tooth decay.

The CDC, Division of Oral Health highlighted water fluoridation as one of the 10 greatest achievements in public health of the 20th century. Additionally, CDC maintains an up-to-date website with research, statistics, and user-friendly tools for the public to learn about the benefits of water fluoridation - http://www.cdc.gov/fluoridation/.

Given the recent statement by the Department , the Surgeon General will not be releasing a statement addressing the benefits of fluoridation.

- **Can you update the Subcommittee on the actions taken by the HHS Oral Health Coordinating Committee to increase the priority given to oral health across the department, including within NIH? What steps can we expect with FY 13 funds?**

Answer: The HHS Oral Health Coordinating Committee (OHCC) is the principal oral health advisory and coordinating entity for the HHS. The OHCC monitors and coordinates activities across the Department; however, must be made clear that the OPDIVs/STAFFDIVs set agency program priorities.

HHS Oral Health Initiative - In April 2010, under the Assistant Secretary for Health's (ASH), Dr. Koh, leadership, HHS launched the Oral Health Initiative which emphasizes the use of evidence-based practices with a strong focus on prevention. The Oral Health Initiative is continuing and has given increased visibility to oral health and resulted in some important new programs:

- IOM reports on oral health;
- CMS national oral health strategy;
- CDC and NIDCR are collaborating on the development of a national oral health surveillance plan;
- Indian Health Service Early Childhood Caries collaborative;
- Web-based dental research tool to standardize clinical research across institutions;
- Cultural Competency Continuing Education Program for Oral Health providers;
- Head Start Dental Home Initiative, and
- Emphasis on Oral Health as Part of Women's Health Across the Life Span.

National Center for Dental and Craniofacial Research (NIH).- During Fiscal Year 2011, the National Institutes of Dental and Craniofacial Research (NIDCR) at NIH spent $409.6 million on research on dental/oral/craniofacial diseases and disorders. NIDCR focuses entirely on supporting research, research training and dissemination of health information related to oral, dental and craniofacial health and is the federal government's focal point for such research Oral Health as a Leading Health Indicator (LHI). Of 42 topic areas in Healthy People 2020, there are 12 leading health indicators, including oral health. The oral health objective is to increase the proportion of children, adolescents and adults who used the oral health system in the past 12 months.

Leadership - HRSA and CMS have recently added key oral health leadership positions, and have joined the OHCC and are working closely on issues important to their member agencies.

External Stakeholder Meeting - The OHCC held a day-long meeting with 30 non-Federal organizations. The purpose of the meeting was to provide a venue for HHS representatives and external stakeholders to communicate their priorities and activities to one another in order to identify potentially actionable items for new or improved collaboration.

IOM Roundtable Workshop on Oral Health Literacy – A first ever IOM workshop focusing on oral health literacy was held on March 29, 2012. .
In its advisory role to the ASH, the OHCC recommends the OPDIVs/STAFFDIVs prioritize the use of FY13 funding on the following areas of focus in oral health:

- Integrating Oral Health into Primary Health Care
- Coordinating Oral Health Efforts across HHS
- Reducing Disparities
- Increasing Access to Care
- Improving Communication and Health Literacy
- Enhancing Public/Private Collaboration around Oral Health
- Extending Research
- Improving and Sharing Data

- **Can you detail how the National Center for Advancing Translational Science (NCATS) plans to engage all of the NIH Institutes and Centers in the opportunities it puts forward, particularly given that they were all tapped to contribute to the formation of the new Center?**

Answer: NCATS will be a hub for catalyzing advances in translational sciences at NIH and, thus, there has been and will be numerous means for communication, coordination, and collaboration between NCATS and the other NIH Institutes and Centers (ICs). NIH was very careful when developing the NCATS mission to ensure that the Center would facilitate, and not duplicate, other translational research activities supported by NIH. To do so, NIH has held numerous stakeholder meetings that included NIH IC representation. Specifically, a working group of several IC directors, including those most involved in translational research, clarified the need for a new effort focused on the discipline of translation, providing tools and resources. This IC input was instrumental in establishing NCATS.

There are several examples that demonstrate how we are continuing to engage all of the NIH ICs. Through our Clinical and Translational Science Awards (CTSA) program, we have encouraged all ICs to include language in their funding opportunity announcements that CTSA resources are available for their NIH-funded investigators. In addition, the next Funding Opportunity Announcement is being developed with significant input from the NIH ICs. NCATS' Therapeutics for Rare and Neglected Diseases (TRND) program has active input from the ICs. For example, the TRND Trans-NIH Advisory Group (TAG), made up of program staff and leadership from NIH ICs, advises TRND on potential program synergies via the leveraging of existing IC programs and provides TRND with disease-specific expertise for projects being conducted. TAG also actively engages IC involvement in projects on any of several levels, e.g., as liaisons to TRND project teams, for project co-funding or for IC adoption of TRND projects. Also, TAG assists with identifying clinical and other resources to carry projects to a New Drug Approval (NDA) post-TRND, and importantly, to serve as a two-way conduit of information between TRND/NCATS and the other NIH ICs. In general, in studying the process of translational science, NCATS will rely on disease-specific projects funded by the categorical ICs to serve as test beds for validating innovative new methods and technologies.

The NCATS Rare Diseases Clinical Research Network (RDCRN) is collaborating with eight other ICs (NCI, NICHD, NHLBI, NAID, NIAMS, NIDCR, NIDDK, and NINDS) to facilitate clinical research in rare diseases through support for collaborative clinical research in rare diseases, training of clinical investigators, and pilot and demonstration projects.

In addition, all ICs are given the opportunity to jointly participate in funding opportunities developed by other ICs. Therefore, as NCATS develops and issues future funding opportunities, other ICs will be able to participate.

Madame Secretary, I'd like to raise a financial management issue where CMS has worked with US industry to develop and implement a single computerized accounting system to replace previously separate systems that handled Medicare contractor and Medicaid payments.

I understand that the "HIGLAS" system is saving taxpayers millions of dollars and has increased government efficiency. I think it's very important for the Members of this Committee to know about this success story that has been on schedule and on budget from the beginning.

- **Can you tell us how this is working to increase the "netting" of receivables owed by Medicare providers to the government?**

Answer: Prior to CMS implementing The Healthcare Integrated General Ledger Accounting System, or "HIGLAS," there was no automated way to ensure that Medicare provided payments were offset (or netted) against any debts that were outstanding to the Medicare program. CMS developed and implemented HIGLAS so that each financial payment made to a Medicare Provider was first "netted" against what they owe Medicare before calculation of the final payment amount. Standardizing the financial processes and requiring "netting" to be performed prior to payments has reduced the initial amounts paid from the Medicare Trust Funds. By improving the accuracy of payment amounts prior to disbursement, there has been a reduced need for recoupment, or "pay and chase" efforts. "Netting" accounts receivable against accounts payable has resulted in funds being retained in the Medicare Trust Funds that have totaled approximately $39.1 billion since 2005.

- **How has this system helped to improve Medicare debt collection and referral activities?**

Answer: HIGLAS has helped to improve Medicare debt collection and referral activities through having increased reporting capabilities and robust financial data. With earlier access to financial information, the collection of debt begins sooner and in many cases is now automated. Automating the accounting practices for Medicare claims processing entities enables CMS to quickly identify collectible debt and take swift recoupment actions. Automation has also accelerated the process of sending all required debt information into the Debt Collection System for further collection activity. Since implementation of this capability in May 2011, Medicare has recouped approximately $14.6 million in Medicare overpayments from Medicare providers/suppliers through this program. In addition, CMS participates in Treasury's Federal

Payment Levy Program and Treasury Offset Program to recoup delinquent tax and non-tax liabilities through reductions in Medicare payments. On a nightly basis, HIGLAS interfaces with Treasury's databases to recoup delinquent Federal debts. Since implementation in October 2008, HIGLAS has collected approximately $207 million of delinquent debt. The recoupment for Treasury is comprised of $154 million of tax debt and $53 million of non-tax debts.

- **How has it worked to reduce Medicare contractor overpayments and create audit trails for Medicare payments?**

Answer: HIGLAS has helped reduce Medicare contractor overpayments by implementing various automated collection processes such as "Netting", and providing for automated integration with the Non-Treasury Disbursing Officeand Debt Collection Improvement Act programs. Additionally, the ability to produce demand letters for amounts owed to the Government, based on immediate financial transactions, allows CMS to promptly pursue collections from providers. As with any financial management general ledger system, HIGLAS maintains and provides audit traceability for all data transactions. Detailed audit reports are maintained to provide traceability of overpayments and collection activities for all debts.

- **How much additional interest was earned in Medicare Trust Funds due to your implementation of HIGLAS since 2005?**

Answer: CMS has calculated that additional interest of approximately $367 million was earned on Medicare Trust Funds due to the implementation of HIGLAS in 2005.

- **Can you tell us when the system will be completely integrated nationally and what are the plans for maintaining the system going forward?**

Answer: Implementation for Medicare financial transactions is targeted for completion near the end of April, 2012. Additional CMS accounting capabilities will be implemented in December, 2012. Maintenance of the system capabilities will require software upgrades in the future to allow compliance with new legislated changes. CMS provides a continual assessment of HIGLAS and employs the services if an Independent Verification and Validation contractor. CMS makes necessary changes to the system through Configuration and Change Management, and performance testing practices, in order to maintain its efficiency.

- **Are there ways to use this same approach to work with industry in improving internal controls in other areas overseen by the Department?**

Answer: HHS has consistently worked with industry and is utilizing industry solutions to enhance our overall financial management. We recently implemented Oracle's Hyperion solution that enables visibility of financial information across all of HHS, which was not previously available for senior leaders. We are currently working to implement Oracle's Business Intelligence solution. We anticipate this solution will provide the capacity for improved fiscal management and management control at the Department level.

Questions for the Record
From Rep. Jack Kingston

PPACA

High Risk Pools

1.) Last week, CMS released a report on the implementation of the newly created high risk pools, which received a direct appropriation of $5 billion. The report highlights average premium costs for individuals enrolled in the new federal pools are twice as much as the costs for state plans that were already in existence before PPACA. CMS claims this is because the federal pools service sicker patients. However, a press report cited one state sought additional federal resources to operate the new pool because individuals only purchased plans long enough to cover services demanded then discontinued paying premiums.

In light of the recent CMS report citing the new PPACA pools spend twice as much as high risk pools previously in place and press reports acknowledging patients in some cases were gaming the system, driving up costs, what measures is the Administration taking to control costs and incentivize program integrity?

Answer: The Pre-Existing Conditions Insurance Plan (PCIP) program is helping the sickest of the sick. As enrollees must have been uninsured for at least six months, they are likely to have delayed or deferred care for their pre-existing condition(s) – which may have caused their condition(s) to worsen, thereby resulting in an immediate need for care when the patient receives health coverage. In addition, PCIP covers pre-existing conditions immediately upon enrollment, unlike many State high-risk pools which impose certain restrictions. Even with better benefit, enrollee premiums aer generally lower in PCIP than in the State high-risk pools.

CMS is working closely with the State-based PCIPs, as well as with the administrators of the Federal PCIP, to monitor the enrollment growth and claims costs in the program, and seek the most cost-effective ways to provide comprehensive coverage to a population of enrollees with pre-existing conditions who have been shut out of the private insurance market. To prevent individuals from gaming the system, PCIP enrollees only receive services if they have paid their monthly premiums within the timeframe designated by each PCIP contractor. For instance, in the Federal PCIP, enrollees must pay their monthly premiums by the 15th of the prior month to receive coverage by the 1st of the following month. CMS staff work with each PCIP contractor to ensure appropriate monitoring processes are in place to allow only qualified individuals who have paid their monthly premiums receive coverage through the PCIP program. Further, gaming is difficult because a PCIP applicant must have not had health coverage, including other PCIP coverage, for six months before enrollment.

In addition, each State contract places a limit of 10 percent on administrative costs over the life of the program. As you know, the Affordable Care Act limited private sector insurance programs to 20 percent administrative costs for the individual and small group markets, so PCIP contractors are required to be twice as efficient in administering their programs as private sector insurers. CMS designated account managers to monitor State spending to ensure it remains within the 10 percent limit. Each State must operate within a fixed allocation for the duration of

each year of the program, and a detailed budget proposal is required for each period of performance. These CMS staff work with states on a continuous basis, through review of monthly financial reports and regular conference calls, to assess where each State's spending is relative to its expected costs. CMS also requires each PCIP contractor to submit an independently audited annual financial report detailing the finances of the State PCIP.

Exchanges

2.) Secretary Sebelius, you testified health insurance premiums will decrease once the exchanges are operational in 2014. However, Secretary Geithner recently requested an additional $111 billion for the exchange subsidies. This is in addition to the nearly $900 million increase requested by HHS in the FY 2013 budget to implement the exchanges and the $1 billion directly appropriated to the agency when PPACA passed. Could you please explain why the additional funds are needed for the subsidies? Are the subsidies actually lowering the actual cost of premiums or simply shifting the increasing costs of health care to the federal taxpayers? Could you please explain how the exchanges will decrease health insurance premiums, particularly given the Congressional Budget Office projects premiums will increase between 10 to 13 percent even after the health exchanges have gone into effect?

Answer: Approximately half of the $111 billion increase for premium tax credits related to Exchanges results from legislative changes enacted in 2011, primarily P.L. 112-56, which changed the definition of modified-adjusted gross income to include certain Social Security income. This legislative change resulted in shifting individuals previously eligible for Medicaid into the Exchange premium tax credits. The remaining difference is attributable to technical changes to Treasury's revenue estimating model that are designed to improve its overall accuracy. Those changes impact all income tax modeling and were not implemented just for purposes of calculating the cost of the premium tax credit. One example of the technical changes involves the projection of the distribution of income across the U.S. population, which resulted in the composition of families projected to claim premium tax credits being somewhat older and lower-income than previously projected. These changes do not reflect fundamental changes in underlying assumptions regarding utilization of premium tax credits or the cost of providing coverage for a given person in the Exchanges.

The primary mechanisms by which Exchanges will lead to decreased premiums include increased competition across health insurance issuers, decreased administrative costs to find and enroll consumers, and combining individuals into a single risk pool. CBO believes the latter two will reduce premiums by up to seven percent each. In addition, a report recently released by CBO and Joint Committee on Taxation reflects a decrease in estimated costs related to Exchange premium tax credits and cost-sharing reductions, primarily due to a projected reduction in premium costs.

IPAB

3.) I know that in IPAB's enacting legislation it says the Board should focus on recommendations to improve quality of care, but the legislation mandates no quality of care goals; only spending cut goals. Now, the folks who will be judging the Medicare spending and thresholds for IPAB—the Medicare actuaries—scored most of the provisions

in PPACA focused on improving quality as yielding 0 savings, even over the course of a decade. Given that the scorekeepers see little savings from quality of care improvement initiatives, it seems likely that IPAB will likely not focus on such initiatives, but instead will focus on provider payment cuts, something CBO has already stated IPAB will likely do. Does it worry you that because of the way IPAB is designed, which mandates that savings must be achieved in a short one-year time frame, that the kinds of decisions IPAB will essentially be forced to make will be year-after-year provider payment cuts? How is it that IPAB can actually improve quality when it is set up in such a way?

Answer: IPAB is required by law to make recommendations that would reduce excess cost growth in Medicare while also focusing, to the extent feasible, on improving health outcomes and protecting Medicare beneficiaries' access to necessary care. IPAB is instructed, to the extent feasible, to include recommendations that promote integrated care, care coordination, prevention and wellness, and quality and efficiency improvement. IPAB will also, to the extent feasible, consider the effects of the recommendations on providers of services and suppliers and target reductions in the Medicare program spending to sources of excess cost growth. Scorekeepers, including both the Congressional Budget Office and the CMS Office of the Actuary, are prudently conservative in attributing savings to new initiatives before they have been fully tested and carefully evaluated. The Affordable Care Act provides for the development and testing of new financing and care delivery models designed to both improve quality and reduce costs. The new Center for Medicare and Medicaid Innovation is engaged in developing and testing a broad array of such models designed to improve care delivery and enhance efficiency. As evaluations of the new care delivery models become available over the coming years, IPAB will be able to develop its recommendations to focus on those models that evidence shows can both improve quality and generate efficiency related cost reductions, which then may be reflected in scored savings. Moreover, Congress can enact alternative measures to strengthen the Medicare program in lieu of IPAB's recommendations.

4.) Some have said that one desirable feature of the IPAB is that it will get the politics out of Medicare. However, interest group politics played a role in the formation of IPAB since nearly 50 percent of Medicare spending is off the table in terms of payment cuts till 2019. Further, the Administration is poised to have significant influence over IPAB. For example, there are three Administration officials that will serve on IPAB as ex-officio members (Secretary of HHS, CMS Administrator and HRSA Administrator) and although they cannot vote, they would undoubtedly exert influence over IPAB decision-making. Second, the President is given the power to appoint nominees to serve on IPAB and in the event that his nominees are not confirmed by the Senate, he has the option to recess appoint members to serve. In addition, in the event that IPAB does not put forth a recommendation, the Secretary of HHS is required to put forth a recommendation instead. So, despite the fact that some believe politics will be out of the equation with IPAB, politics has been and will likely continue to be very much a part of IPAB. Do you believe politics will in fact be removed from IPAB given the amount of influence the Administration would have over IPAB?

Answer: IPAB will be composed of fifteen experts including doctors, consumers and patient advocates. IPAB members will provide a mix of different professionals, broad geographic

representation, and a balance between urban and rural representation. Moreover, Congress can enact alternative measures to strengthen the Medicare program in lieu of IPAB's recommendations. The President is committed to working with Congress to appoint members of the IPAB who will carry out the required duties of the board, including making timely recommendations to Congress.

Categorical Eligibility

5.) HHS has provided funds to most, if not all, of the states to modernize their Medicaid eligibility systems in anticipation of Medicaid expansions and the health insurance exchanges. It seems to me with this amount of federal investment, that these systems could also be used to verify income for other federal and state income-based programs. For example, if a family is on Medicaid they can enter the WIC program without showing any income documentation to the WIC program. Could these modernized Medicaid eligibility systems be used to verify income for the WIC program, which is nationally set at or below 185 percent of the Federal Poverty Level? Could they be used for other programs, like to verify income for free and reduced-priced participation in the School Lunch Program in order to reduce the use of categorical eligibility without an increase to administrative costs?

Answer: States are now eligible to receive an enhanced match of 90 percent for design, development, and installation under Medicaid through 2015 and 100 percent Federal funds for the design of their eligibility systems for the Exchanges to update and build eligibility systems in preparation for 2014. On August 10, 2011, HHS, along with the U.S. Department of Agriculture (USDA), announced a time-limited, specific exception to the cost allocation requirements set forth in OMB Circular A-87. This exception allows Federally-funded human services programs (e.g. Supplemental Nutritional Assistance Program (SNAP), Temporary Assistance to Needy Families (TANF), Child Care, and others) to benefit from investments in the development of State eligibility-determination systems for State-operated Exchanges, Medicaid and CHIP. These common business processes and technical services that Medicaid, CHIP, and Exchange programs may require to determine program eligibility, such as income verification, are also common business processes and technical services to determine program eligibility for many human services programs. Any service, expansion of service, or increase in capacity beyond that required for the health programs, must be cost allocated to the benefitting program, consistent with the current practice under OMB Circular A-87.

This policy will assist States that want to develop integrated systems, which could provide better customer service to families, promote more seamless coordination across health and human services programs, reduce the number of duplicative State systems, and enhance program integrity efforts related to eligibility determinations.

To further promote coordination between Medicaid and other income-based programs and reduce administrative costs, the final rule implementing Medicaid eligibility expansion requires States to request information related to financial eligibility from SNAP and other programs when useful to verifying financial eligibility and set out the standards in the rule to establish an appropriate basis for States to assess the usefulness of SNAP, as well as other data in verifying financial eligibility. Longstanding Medicaid regulations have allowed Medicaid agencies to

delegate income eligibility determinations to other State agencies (such as agencies administering TANF and SNAP programs) as well as to local Medicaid offices (such as those administered by counties). These delegations will continue to be permitted under this final rule, although the Single State agency's authority and oversight responsibilities are identified with greater specificity.

Anti-Lobbying Restrictions

7.) All federal funds are subject to 18 U.S.C. 1913, which expressly prohibits the use of federal funds for lobbying activities. Further, HHS issued AR-12 that clearly restricts grantees from using federal funds to "influence action in regard to a particular piece of pending legislation." This includes lobbying for or against pending legislation as well as indirect grass roots lobbying on legislation at the federal, state and local levels. Despite these strict anti-lobbying guidelines, funds appear to have been used to lobby for sugar sweetened beverage taxes. What steps will you take to ensure a full investigation as to whether grantees violated the anti-lobbying restrictions, and what punishment will the Administration place on grantees and officials who violated the federal law? Specifically, will the Administration place grantees that violated 18 U.S.C 1913 on the federal grantee banned list? What measures is HHS taking to better review grant applications to ensure federal funds are not awarded for projects that violate federal law? Given the fact some HHS grantees violated the anti-lobby restrictions, could you please explain why the President's FY 2013 budget removes language from the FY 2012 appropriations bill clarifying the prohibition of funds for lobbying activities?

Answer: HHS is committed to ensuring the proper use of appropriated funds, and to ensuring awardees' compliance with all applicable regulations and statutes related to lobbying activities, such as Office of Management and Budget (OMB) Circular A-122: Cost Principles for Non-Profit Organizations; OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Governments; our own policy regarding lobbying activities; and 18 U.S.C. § 1913: Lobbying with Appropriated Moneys.

For the FY 2013 President's Budget, a review was conducted of general provisions of the FY 2012 Consolidated Appropriations Act, including Section 503. Provisions deemed duplicative of existing law were removed. HHS programs have required grantees to comply with all existing laws in using federal funds.

HHS awardees are informed about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. Not only are the restrictions noted within HHS funding opportunity announcements, the lobbying prohibition is also included within the terms and conditions to which each awardee agrees prior to receiving federal funds. Violations of grantee terms and conditions may result in actions such as restriction on award, special monitoring procedures, or award termination.

In addition, HHS staff monitor the use of federal funds by awardees using tools such as on-site review and risk mitigation plans. HHS staff regularly interact with grantees to ensure that they are implementing the activities and strategies set forth in the grantee's work plan and that

grantees are adhering to administrative requirements, including adhering to provisions relating to lobbying.

Applicable lobbying restrictions do not prohibit awardees from interacting with policymakers. Federal law allows many activities that are not considered lobbying and that community awardees may decide to pursue. For example, awardees may use funds to disseminate information about public health programs and science-based solutions and to implement specific programs, such as evidence-based educational materials and media on the health effects of increasing physical activity or decreasing exposure to secondhand smoke.

At HHS, we are committed to fulfilling the mandates from Congress to empower communities to pursue high-quality, science-based programs that make a real difference in the health of Americans. We take our responsibility as stewards of taxpayer dollars very seriously, and we are committed to enabling awardees' success and to ensuring that federal funds are used efficiently and appropriately.

Children's Hospital Graduate Medical Education (CHGME)

8.) The President's FY 2013 budget provides funding for only direct costs of the CHGME program and not indirect expenses, which constitutes two thirds of the training costs. CHGME's currently supports 49 percent of all pediatric residents. Given the shortage of pediatricians and pediatric specialists that already exists and the increasing demand for these services, what alternatives is HHS taking to address the inevitable unmet need created by the proposed elimination of indirect reimbursements?

Answer: We recognize the vital role that children's hospitals and pediatric providers play in providing quality health care to our Nation's children.

The FY 2013 CHGME funding level continues to support direct costs for training pediatric residents at independent children's hospitals. This covers the costs of resident salaries, expenditures related to stipends and fringe benefits for residents, salaries and fringe benefits of supervising faculty, cost associated with the GME training program, and allocated institutional overhead costs.

The FY 2013 Budget retains the incentive to maintain total resident levels. Additionally, the FY 2013 President's Budget includes $5 million to implement the Pediatric Specialty Loan Repayment (PSLR) Program that was authorized in the Affordable Care Act. Under this program, loan repayment agreements will be authorized for pediatric specialists who agree to work in underserved areas.

While both the CHGME Payment and the PSLR programs support the pediatric medical workforce, each of these programs has a different focus . The CHGME Payment Program serves the purpose of providing residency training in Children's Hospitals through the payments made to Children's Hospitals, while the PSLR program is designed to assist pediatric specialists more directly and increase the number of pediatric specialists in underserved areas.

Abortion Drugs

9.) There have been growing concerns regarding the usage of RU-486 over telemedicine networks without direct physician assessment as seen in a recent new article from The Washington Times. There is also concern that the rate of usage of this procedure is increasing. Have any federal funds authorized under the Telemedicine or Title X programs been awarded to grantees to dispense or prescribe abortion drugs, such as RU-486 without a licensed physician physically present? If so, please provide a list of recipients who have received such funding.

Answer: No federal funds have been awarded to grantees to dispense or prescribe abortion drugs, such as RU-486, regardless of a licensed physician physically being present. Specifically, Section 1008 of the Title X statute, 42 U.S.C 300a-6, states: "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." Therefore, Title X funds cannot be used to fund either medical abortion or surgical abortion.

Home and Community Based Service Waiver Program

10.) Section 6071 of the Deficit Reduction Act of 2005 (P.L. 109-171) was designed to assist States to balance their long-term care systems and help Medicaid enrollees transition from institutional settings to appropriate home and community based service settings. This program was extended through September 30, 2016 by the Patient Protection and Affordable Care Act (P.L. 111-148) in 2010. Does the underlying legislation contained in the 2005 Deficit Reduction Act (P.L. 109-171) or legislation contained in P.L. 111-148 in any way restrict CMS's ability to broadly define a "home" for purposes of transitioning qualified Medicaid enrollees into appropriate settings under the Home and Community Based Waiver program? If so, how and does the underlying legislation in any way impact current efforts to provide and expand person centered care to meet the growing needs of different populations?

Answer: A primary feature of the Money Follows the Person program is the enhanced Medicaid reimbursement rate that is available to participating states for the services provided to Medicaid enrollees who transition from institutions to "qualified residences." A "qualified residence" is defined in MFP's authorizing statute as: a home that is owned or leased by the Medicaid enrollee or the enrollee's family member; an apartment with an individual lease that has lockable access and egress, and which includes sleeping, bathing, and cooking areas over which the enrollee has domain and control; and a residence, in a community-based residential setting, in which no more than four unrelated individuals reside. This definition was contained in the original Deficit Reduction Act provision and was not modified by the Affordable Care Act's amendments. CMS may not permit Medicaid payment to a State at the enhanced rate available under the MFP program for services that are provided to a Medicaid beneficiary who is not residing in a residence that meets the statute's definition of a "qualified" residence.

The MFP statute does not mandate that its definition of a "qualified residence" be applied in the context of other Medicaid home and community-based services (HCBS) coverage. However, CMS believes that the purpose of this restriction in the MFP program is to ensure that Medicaid enrollees who are leaving institutions are transitioning to locations in which their independence and community integration may truly be maximized. CMS considers this to be an important

goal, and the agency is striving to advance this goal across the spectrum of Medicaid HCBS programs. Elements of the MFP program's "qualified residence" definition offer a useful starting point in this endeavor.

Questions for the Record
From Rep. Jeff Flake

Premium Rates:
The President championed the fact that the Affordable Care Act- if passed- would decrease premiums for the average family by $2,500.

Question: Do you have any evidence to suggest that every family's premiums have gone down by up to $2,500, as the President promised?

Answer: Most of the market reforms that will impact premium costs will not be in effect until 2014.

Question: In September 2010, you claimed at a National Journal briefing that premium *increases* "are likely to continue to be somewhat substantial." How does your statement square with the President's promise that he would "cut" premiums – meaning they would go down?

Answer: Most of the market reforms that will impact premium costs – with Exchanges and premium tax credits being the primary change - will not be in place until 2014. Until the Exchanges are implemented, consumers have limited ability to compare across options to get the best value for their premium dollars, and health insurance issuers have less incentive to compete based on price. That is why we may expect to see premium increases in the next couple of years leading up to the opening of Exchanges.

Question: In July 2008, Jason Furman – who remains a senior economic advisor within the Administration – told the New York Times that "we think we could get to $2,500 in savings by the end of the first term, or be very close to it." Will this pledge to cut premiums for every family by $2,500 be met by next year, as the Administration promised? If not, when do you expect to hit this goal?

Answer: Assumptions about premium rate reductions rely on implementation of insurance market reforms, particularly the Exchanges, which do not take effect under the legislation until 2014. We may not realize premium decreases until such time as Exchanges are fully operational.

Question: In 2008, Barack Obama promised that his health plan would cost "between $50-65 billion a year when fully phased in." But CBO estimated that Obamacare will cost $229 billion in 2020 and $245 billion in 2021. What is responsible for this four-fold increase in expected spending on the law?

Answer: According to a recent CBO and JCT report entitled, "Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act," the net costs of insurance coverage provisions in FY 2020 and FY 2021 are $151 billion and $161 billion respectively. These estimates reflect the coverage spending and revenue provisions only, and do not include the other provisions of the Affordable Care Act that are projected to reduce the deficit. CBO estimates indicate that the ACA will continue to lower the deficit by more than $100 billion over the next decade.

Question According to a CBO report released March, 2012, "the current estimate of the gross costs of the coverage provisions ($1,496 billion through 2021) is about $50 billion higher than last year's projection." Can you provide some more details on what is responsible for this increased projection? Does the Administration have any concerns with this increase?

Answer: CBO and the Joint Committee on Taxation (JCT) have recently incorporated technical changes to their Affordable Care Act coverage estimates that impact both outlays and expected revenues. According to a recent CBO and JCT report entitled, "Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act," the revised estimates of the coverage provisions of Affordable Care Act lead, "to the small decrease in the net 10-year tally" as compared to last year's estimates. CBO estimated that the gross costs of the provisions increased, but estimates of the other budgetary effects of the coverage provisions – which partially offset the gross costs – also changed since last year leading to a net decrease in the deficit.

Accountable Care Organizations Questions:
Secretary Sebelius, there has been more attention on ACOs as of late due to concerns that instead of empowering doctors and patients, ACOs are actually encouraging health care providers to consolidate. Through these consolidations hospitals are increasing their market share and consequently negotiating higher reimbursements that are passed along as higher costs on consumers and ultimately the taxpayer.

Last fall, Federal Trade Commissioner J. Thomas Tosch warned that the overall result of the ACO may reform may "be higher costs and lower quality health care- precisely the opposite of its goal."

Question: Madam Secretary, is the model that the Administration envisioned for ACOs working? If so, please explain how?

Answer: While it is too early to draw any conclusions about the success of ACOs in improving quality and lowering costs, CMS believes that beneficiaries will likely benefit from the ACOs' increased investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

Question: Did the Administration have any concerns that incorporating ACOs in the health care law could lead to the formation of what are essentially health care monopolies that increase overall health care costs on all Americans?

Answer: CMS believes competition among the Medicare ACOs will likely foster improvements in quality, innovation, and choice for Medicare beneficiaries. CMS intends to ensure that appropriate monitoring of the competitive effects of ACOs is underway by coordinating closely with the antitrust agencies throughout the application process at all stages of participation by Medicare ACOs. CMS is providing aggregate claims data to the antitrust agencies to assist in their monitoring efforts to ensure ACO formation and implementation does not have a detrimental effect upon competition. In addition, the antitrust agencies have existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct.

Question: How does it affect your budget if ACOs are actually increasing the cost of health care, versus saving money as they were originally intended to do?

Answer: CMS believes the implementation of ACOs will result in better coordinate care for beneficiaries, ending duplicative tests and other costs of inefficient care models. As ACOs begin to redesign processes to focus on coordinating care for populations, CMS expects they will lead to better care and lower growth in Medicare expenditures over the next several years. CMS' regulatory impact analysis for the final rule included a median estimate of the Shared Savings Program financial impact for calendar years 2012 through 2015 as a net Federal savings of $470 million.

Question: Is the Administration doing anything to infuse competition to keep costs low?

Answer: In addition to ensuring that appropriate monitoring of the competitive effects of ACOs is underway by coordinating closely with the antitrust agencies throughout the application process and at all stages of participation by Medicare ACOs, the Center for Medicare and Medicaid Innovation is testing the Advance Payment ACO model. This model provides selected participants in the Medicare Shared Savings Program advance payments that would be recouped from any shared savings they earn. The Advance Payment ACO model is targeted to organizations whose ability to invest in infrastructure and redesigned care processes would be improved with additional access to capital, particularly small rural and physician-based organizations. CMS believes the participation of these organizations in the Medicare Shared Savings Program will likely lead to additional competition in the ACO market.

Question: Do you have any evidence to suggest that ACOs are actually lowering the cost of health care? Could you please share this information?

Answer: The testing of the Pioneer ACO model began on January 1, 2012 and the first ACOs participating in the Medicare Shared Savings Program start on April 1, 2012. Because the ACOs have just started, at this time we do not have sufficient data to determine the financial effect of ACOs on Medicare expenditures.

Question: How much has the Administration spend thus far on promoting ACOs?

Answer: CMS/Office of Communications' has spent $518,095 thus far in development of the ACOs' communications plan and research.

Question: Over the last 10-15 years we have seen massive consolidation in the health care industry with building of health care systems and monopolies and oligopolies in regional markets. This has resulted in large entities that have become less efficient than their smaller counterparts and pricing power due to their market dominance. Isn't this one of the reasons the consumer has been hurt and what are the administration plans to correct this problem?

Answer: As noted in the response to the previous questions, CMS believes that competition among the Medicare ACOs will likely foster improvements in quality, innovation, and choice for Medicare beneficiaries. CMS intends to ensure that appropriate monitoring of the competitive effects of ACOs is underway by coordinating closely with the antitrust agencies throughout the application process and the operation of the Medicare ACOs. In addition, CMS believes the testing of the Advance Payment ACO model will likely lead to increased participation by smaller organizations in the Medicare Shared Savings Program.

Head Start Questions:
The President's requests over $8 billion for Head Start programs, which amounts to an $85 million increase of over FY2012. The budget justification for this increase states:

"This investment will also provide resources to effectively implement new regulations that require grantees that *do not* meet high quality benchmarks to compete for continued funding, introducing an unprecedented level of accountability into the Head Start program."

Question: Secretary Sebelius, does this mean that HHS will award grants to grantees that don't meet these 'high quality benchmarks'?

Answer: Only grantees that meet high quality benchmarks will be awarded funding without competition. Grantees that do not meet these benchmarks are required to participate in an open competition if they wish to continue to receive funding. Panel reviewers will assess the applications received for funding in each service area, and score them against clear evaluation criteria to determine whether they are capable of providing high quality services.

Question: Under these new regulations Head Start grants will be awarded on a competitive basis? Are these grants currently awarded on a competitive basis?

Answer: New Head Start grants are awarded through a competition, but before the most recent Head Start reauthorization on-going Head Start grants were funded on an indefinite basis. This means that prior to the implementation of the Designation Renewal System, current Head Start grantees received at least the same level of funding as was provided to them in the previous year unless the Office of Head Start could legally terminate their funding for poor performance. With the implementation of the Designation Renewal System, grantees that do not meet high quality benchmarks will have to compete to continue to receive funding.

Question: Could you please clarify what specific regulations HHS will be implemented to 'introduce a new level of accountability into the Head Start program'?

Answer: The Policies and Procedures for Designation Renewal of Head Start and Early Head Start Grantees (45 CFR 1307) sets forth the new processes for determining whether a Head Start or Early Head Start grantee is providing high quality services to meet the educational, health, nutritional, and social needs of children and families they serve, is meeting the program and financial requirements and standards described in section 641(A)(a)(1) of the Head Start Act, and thus qualifies for funding for five years without competing for such funding as required under section 641(c) of the Head Start Act.

Grantees that do not meet high quality benchmarks will be required participate in an open competition for a grant to continue operating in their service area. The rules governing the process for competition of Head Start and Early Head Start grantees are outlined in 45 CFR 1307.

The process of determining whether a grantee is providing high quality Head Start and/or Early Head Start services, and the requirement that such grantees to compete against other organizations for funding to continue providing Head Start or Early Head Start services demonstrates an unprecedented level of accountability in the Head Start program.

In addition to Head Start, the President's budget also requests $300 million for a new child care quality initiative and additional monies for the Early Learning Challenge Fund within Department of Education. After reading the descriptions of these programs, it appears they all have a similar objective: helping prepare students for educational success.

Question: Could you shed some more light on why there are three different initiatives and in general what your department is doing to streamline programs to avoid duplicating efforts?

Answer: The FY 2013 Budget supports an important set of reforms to improve health and safety and raise the bar on quality in early learning programs by proposing improvement in the three key Federal programs for early learning – Head Start, the Child Care and Development Fund (CCDF), and the Race to the Top – Early Learning Challenge (RTT-ELC). Each of these initiatives targets different aspects of the early childhood system and each has a different funding mechanism.

The additional funding requested in Head Start will support the new designation renewal process, by which grantees determined not to be providing high quality services are required to participate in an open competition if they wish to continue providing Head Start services. These funds will support transitions from incumbent grantees to new grantees in order to minimize the potential for service disruption and provide support for additional monitoring of new grantees. The FY 2013 request also includes a cost of living adjustment to maintain services for the same number of children currently being served.

In CCDF, the budget includes $300 million in funding for a Child Care Quality Initiative. This initiative is different than RTT-ELC as it would make funding available to all States to improve the quality of child care. At the same time, it is also complementary in purpose to both the Head Start and RTT-ELC investments since some funds would be used to invest directly in programs and teachers to help them meet higher quality standards that can help children on the path to school success. States have told us that funding for this purpose is critical to help programs and teachers "move up" within the quality improvement and systems infrastructure. In addition, a portion of this funding will also be competitively awarded to States and Tribes that demonstrate a strong commitment to making large strides in their ability to implement a quality improvement rating system that communicates reliable, program-specific quality information to parents.

The RTT-ELC program is a competitive grant program administered jointly by the Department of Education and the Department of Health and Human Services. Grants are awarded to States to promote the development of a sustainable infrastructure to support high-quality early learning programs and systems. The funding provides the resources to improve coordination among all early learning programs in the state and to implement a specific set of quality reforms across all of these programs. The Departments work very closely in order to minimize duplication of efforts. Staff meet regularly to coordinate policy development and streamline technical assistance investments.

Funds requested for the RTT-ELC will support efforts to design and implement integrated and coordinated systems of high-quality early learning programs and services. These funds will help to align and raise standards for children, existing early learning programs, and the early childhood workforce; improve training and support for the early learning workforce through evidence-based practices; and build robust evaluation systems that promote effective practices and programs, include kindergarten entry assessments, and provide transparency so that families can make informed decisions and policy makers can direct resources.

FSA/HSA

The Affordable Care Act bans FSA and HSA funds from being used to purchase over-the-counter medications. It is my understanding that This "medicine cabinet tax" is just one example of how these traditionally flexibly plans are being hamstrung.

a. From the larger picture, can you explain the rationale behind this tax?

Answer: It is my understanding that over the counter drugs can still be purchased with FSA funds and HSA funds on a tax-favored basis if prescribed by a doctor. For more specific information regarding these provisions, I would refer you to the Treasury Department's Office of Tax Policy.

b. Do you think the prohibition on American's using their FSA and HSA funds to purchase over-the-counter products should be repealed?

Answer: For more specific information regarding these provisions, I would refer you to the Treasury Department's Office of Tax Policy.

Lobbying Ban Questions:
Secretary Sebelius testified previously before the Labor-HHS Subcommittee that you fully understood that grantees were not allowed to use federal tax dollars to lobby. In response to questions about CDC grantees lobbying with federal tax dollars, you specifically stated:

> **Secretary Sebelius: "Congressman, I read the same information from the same news source. I can assure you that we will follow to the letter of the law the Federal law which prohibits Federal funds and has, not just in the Recovery Act but consistently, prohibited lobbying with Federal dollars. We will track that very carefully. We have already notified a whole host of folks that that is the law of the land. That was part of the grant application and will continue to be part of the monitoring. Federal funds will not be used for lobbying.**
>
> **Secretary Sebelius: They have been notified that there is an absolute prohibition for using any Federal funding for lobbying. And we will follow up on that very carefully."**

Question: Madam Secretary, do you agree with 18 USC 1913, your previous statements to this committee and with your department's statements in AR-12- that your grantees cannot use federal tax dollars to lobby any government -- federal, state or local?

Question: Assuming we all understand these multiple federal laws and regulations, how will you clarify this rampant confusion in your department and among your grantees?

Question: What steps will you take to ensure that a full investigation occurs regarding any federal tax dollars that were misappropriated for lobbying activity?

Question: And, what punishment will be handed down to grantees and officials that ignored the clear prohibitions of federal law?

Answer: HHS is committed to ensuring the proper use of appropriated funds, and to ensuring awardees' compliance with all applicable regulations and statutes related to lobbying activities, such as Office of Management and Budget (OMB) Circular A-122: Cost Principles for Non-Profit Organizations; OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Governments; our own policy regarding lobbying activities; and 18 U.S.C. § 1913: Lobbying with Appropriated Moneys.

For the FY 2013 President's Budget, a review was conducted of general provisions of the FY 2012 Consolidated Appropriations Act, including Section 503. Provisions deemed duplicative of existing law were removed. HHS programs have required grantees to comply with all existing laws in using federal funds.

HHS awardees are informed about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. Not only are the restrictions noted within HHS funding opportunity announcements, the lobbying prohibition is also included within the terms and conditions to which each awardee agrees prior to receiving federal funds. Violations of grantee

terms and conditions may result in actions such as restriction on award, special monitoring procedures, or award termination.

In addition, HHS staff monitor the use of federal funds by awardees using tools such as on-site review and risk mitigation plans. HHS staff regularly interact with grantees to ensure that they are implementing the activities and strategies set forth in the grantee's work plan and that grantees are adhering to administrative requirements, including adhering to provisions relating to lobbying.

Applicable lobbying restrictions do not prohibit awardees from interacting with policymakers. Federal law allows many activities that are not considered lobbying and that community awardees may decide to pursue. For example, awardees may use funds to disseminate information about public health programs and science-based solutions and to implement specific programs, such as evidence-based educational materials and media on the health effects of increasing physical activity or decreasing exposure to secondhand smoke.
At HHS, we are committed to fulfilling the mandates from Congress to empower communities to pursue high-quality, science-based programs that make a real difference in the health of Americans. We take our responsibility as stewards of taxpayer dollars very seriously, and we are committed to enabling awardees' success and to ensuring that federal funds are used efficiently and appropriately.

Questions For the Record,
From Rep. Cynthia Lummis

The Medicare Modernization Act of 2003 requires the Medicare Boards of Trustees to make an annual determination of whether projected annual general revenue funding exceeds 45 percent of total Medicare outlays in each of the next 7 fiscal years. The Boards' 2011 report projected general revenue financing of Medicare outlays in excess of 45 percent in fiscal years 2011 and 2012. As you are likely aware, this is the sixth consecutive finding of Medicare outlay financing by general revenues in excess of 45 percent.

As you also know, this finding requires the President to submit to Congress legislation to respond to the warning within 15 days of the next budget submission. To quote the Boards' 2011 report on page 54: "revenue increases of at least $25 billion or benefit reductions of at least $46 billion, or some combination of revenue increases and benefit reductions, would be required to reduce the ratio below 45 percent for 2011 and 2012."

Please provide, in writing, a detailed explanation of how the President's fiscal year 2013 budget proposal would reduce the ratio below 45 percent for 2011 and 2012. If the budget proposal does not reduce the ratio below 45 percent for 2011 and 2012, then please provide, in writing, a justification of the Administration's decision not to submit to Congress a legislative response to the Board's Medicare funding warning as is required by the Medicare Modernization Act of 2003.

Answer: The President's Budget strengthens Medicare by implementing payment innovations and other reforms that encourage high-quality and efficient care and improved program integrity,

while preserving the program's fundamental pledge to seniors and individuals with disabilities. These reforms will save approximately $300 billion over the next decade. As such, the President's Budget constitutes a major step forward in maintaining Medicare's long-term sustainability, and addressing underlying issues that triggered the Trustees' fund warning. As noted in the Budget, in accordance with the Recommendations Clause of the Constitution, the Executive Branch considers the requirement to submit legislation in response to the Medicare funding warning to be advisory and not binding. The Administration looks forward to continuing to work with Congress to identify additional opportunities for strengthening Medicare's fiscal position, while maintaining beneficiaries' access to high quality care.

The Administration's economic stimulus website, www.recovery.gov, revealed millions of prevention and wellness dollars used by Centers for Disease Control (CDC) grantees to influence state or local government actions. In response, Congress expanded federal lobbying restrictions on grantees in the FY12 omnibus appropriations bill (Sec. 503).

The Administration FY13 budget proposes to weaken Sec. 503, effectively allowing the use of federal funds to influence proposed or pending regulations, administrative actions, or orders issued by State or local governments. Do you support allowing grantees to use federal funds to influence the enactment of regulations, administrative actions or orders issued by state or local governments? If not, why are you proposing to weaken Sec. 503?

Under current law, there are several provisions that prohibit the use of tax dollars for lobbying purposes.

Under 18 U.S. 1913, no federal tax dollars shall:

> **"be used directly or indirectly to pay for any personal service, advertisement, telegram, telephone, letter, printed or written matter, or other device, intended or designed to influence in any manner a Member of Congress, a jurisdiction, or an official of any government, to favor, adopt, or oppose, by vote or otherwise, any legislation, law, ratification, policy or appropriation [. . .]"**

The CDC's internal grant guidance, Additional Requirement (AR) 12, reinforces the statutory restriction on using federal funds to lobby:

> **"No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature."**

Sec. 503 of the FY12 omnibus states that funds in the act may not be used to:

> **"influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body [. . .]"**

Sec. 503's prohibition includes:

> **"any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control."**

As I stated previously, numerous CDC grantees have publicly disclosed the use of tax dollars for legislative agendas, including the pursuit of tax increases, at the state or local level. I request that you respond to the following points in writing:

- **Please describe your understanding of the various federal anti-lobbying prohibitions (including 18 U.S. 1913, AR 12, Section 503 of the FY12 omnibus, and past fiscal year anti-lobbying riders) and how they apply to CDC grantees seeking to influence state or local government bodies.**

- **If your Department interprets the federal lobbying prohibitions that apply to pre-FY12 grantees differently than FY12 grantees, please explain these differences, including how you intend to enforce the lobbying prohibitions for FY11 grantees that receive continuation funds from the FY12 omnibus.**
- **Please investigate and respond as to whether CDC grantees have misappropriated federal funds for lobbying under your tenure, including details on how you have and how you intend to ensure oversight over grantees to prevent misappropriation of tax dollars for prohibited lobbying activities.**

Answer: HHS is committed to ensuring the proper use of appropriated funds, and to ensuring awardees' compliance with all applicable regulations and statutes related to lobbying activities, such as Office of Management and Budget (OMB) Circular A-122: Cost Principles for Non-Profit Organizations; OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Governments; our own policy regarding lobbying activities; and 18 U.S.C. § 1913: Lobbying with Appropriated Moneys.

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In addition, HHS staff monitor the use of federal funds by awardees using tools such as on-site review and risk mitigation plans. HHS staff regularly interact with grantees to ensure that they

are implementing the activities and strategies set forth in the grantee's work plan and that grantees are adhering to administrative requirements, including adhering to provisions relating to lobbying.

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At HHS, we are committed to fulfilling the mandates from Congress to empower communities to pursue high-quality, science-based programs that make a real difference in the health of Americans. We take our responsibility as stewards of taxpayer dollars very seriously, and we are committed to enabling awardees' success and to ensuring that federal funds are used efficiently and appropriately.

Questions For the Record,
By Rep. Nita M. Lowey

Asthma

I am concerned that in the CDC's proposed consolidation plan, many existing programs would be rendered less effective. For example, the National Asthma Control Program was consolidated with Healthy Homes in CDC's National Center for Environmental Health (NCEH). Many of CDC's asthma program activities are executed outside the home and in the community, and these activities would likely be jeopardized if this program is combined with Healthy Homes. Furthermore, the proposed consolidated programs could lead to a reduction in important activities that by nature don't result in immediate pay-offs for States. This could lead to a serious public health risk, as diseases and conditions would be allowed to progress unnoticed and unaddressed.

- **What effect do you think these consolidations and cuts will have on the asthma programs supported by CDC?**

- **The prevalence of asthma is highest among non-Hispanic black children. What affect will the budget request for NACP have on minority health disparities?**

- **Why did the HHS budget request consolidate programs in CDC which Congress requested not to be consolidated in the FY12 appropriations bill?**

- **What is Dr. Frieden's plan to ensure that the activities of specific program items such as astbma won't get lost within the consolidated proposals?**

Answer: The FY 2013 Budget proposes a new program—Healthy Home and Community Environments—that will incorporate the National Asthma Control Program (NACP) and the

Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The FY 2013 request for the Healthy Homes and Community Environments program is $27.3 million.

The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors. CDC surveillance activities will continue to be used to identify populations at-risk or with significant disparities in order to target interventions. Evidence shows that comprehensive asthma control programs are most effective in improving asthma outcomes and reducing health care costs. One key intervention to manage asthma is to increase use of inhaled corticosteroids, something that will be facilitated in 2014 and beyond through expanded coverage through the Affordable Care Act. CDC will take two years to transition to this new, coordinated approach.

Lead Poisoning
The FY13 request would consolidate the Healthy Homes and Lead Poisoning Prevention Program.

- **How is the Administration going to ensure that the nation's most vulnerable children are tested for lead poisoning and ensure that if those children test positive that treatment and environmental remediation services are provided?**

Answer: The FY2013 President's Budget proposes a new program—Healthy Home and Community Environments—that will incorporate CDC's National Asthma Control Program (NACP) and the Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The FY 2013 request for the Healthy Home and Community Environments program is $27.3 million.

The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors.

- **Given the drastic cuts to CDC's Lead Poisoning Prevention Program that could essentially end all state cooperative agreements, what are your proposed strategies moving forward to ensure that the essential services (emergency response to children with lead poisoning, home inspections that include environmental health components, surveillance, etc.) provided by state and local health departments to vulnerable children are not lost?**

Answer: With FY 2012 funding, CDC's Healthy Homes and Lead Poisoning Prevention Program will continue to provide lead expertise and analysis at the national level and remain a valuable resource to state and local agencies by providing the following:

- Surveillance Support: Provide software and technical assistance to support the Healthy Homes and Lead Poisoning Surveillance System (HHLPSS), which gathers information related to lead and other health hazards in homes.
- Epidemiological Support: Maintain staff to provide expertise and epidemiological support in response to a lead poisoning outbreak.
- Subject Matter Expert Support: Maintain the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The ACCLPP advises and guides the Secretary and Assistant Secretary of the U.S. Department of Health and Human Services and the Director of the Centers for Disease Control and Prevention regarding new scientific knowledge and technical developments and their practical implications for childhood lead poisoning prevention efforts.

Tuberculosis

Tuberculosis (TB) is a serious global concern and the virus is becoming more complex with recent cases of Totally Drug-Resistant TB emerging.

- **Do you agree that maintaining domestic tuberculosis prevention, control and treatment programs is critical to protecting American citizens from this complex and deadly disease?**

Answer: Effective control efforts by CDC and its 68 state and local partners led to the lowest number of overall U.S. TB cases (estimates are 11,182 cases in 2010, or 3.6 per 100,000 population) since national reporting began in 1953. Reflecting program effectiveness, the U.S. consistently ranks among the lowest TB incidence countries in the world. Moreover, while TB drug resistance is increasing globally, with the World Health Organization (WHO) reporting 440,000 cases and 150,000 deaths in 2008, numbers of drug resistant cases in the United States remain stable at less than one percent of all cases (approximately 100 cases per year). In FY 2013, CDC will work with partners to implement programs in a way that maintains a focus on TB control for the most urgent cases, especially outbreaks that have already resulted in deaths or permanent neurological or other damage to health, as well as cases that are multi-drug resistant.

Drug-resistant TB occurs when the bacteria causing TB become resistant to drugs used to treat TB disease. This can occur when treatment is interrupted—for example, when patients do not complete the full course of TB therapy, when providers prescribe the wrong drugs or wrong length of therapy, and when the TB drug supply is unavailable or of poor quality. Drug resistant TB can develop in a patient whose treatment is interrupted, but it is also contagious and can be spread to others. Drug resistance can develop against any drug that is used to treat TB, and is found everywhere in the world. The terms drug resistant, multidrug resistant (MDR), and extensively drug resistant (XDR) refer to the number of TB drugs that have become useless in treating a patient's case of TB.

TB drug resistance remains a serious threat to global health, and it is a major challenge to the goal of eliminating TB in our country. While numbers and rates of TB in the United States are declining, 62.5 percent of U.S. TB cases in 2011 occurred among foreign born persons. A total of 109 cases of multidrug-resistant TB were reported in 2010—the most recent year for which complete drug-susceptibility data were available. Foreign-born persons accounted for 90 (82 percent) of these cases. Four cases of extensively drug-resistant TB were reported in 2011, all occurring in foreign-born persons. These data evidence the higher burdens of TB in other countries.

Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is the third leading cause of death in the U.S. It kills 141,075 Americans annually. Approximately 12 million adults have been diagnosed with COPD, and it is estimated that another 12 million are unaware that they have it. Early diagnosis of COPD leads to better treatment outcomes.

- **What can HHS do to increase early detection of COPD?**

Answer: In 2011, CDC released the Public Health Strategic Framework for COPD Prevention. This Framework identifies four goals for the prevention, detection, and treatment of COPD: (1) surveillance and evaluation: improve collection, analysis, dissemination, and reporting of COPD-related public health data; (2) public health research and prevention strategies: improve understanding of COPD development, prevention, and treatment; (3) programs and policies: increase effective collaboration among stakeholders with COPD-related interests; and (4)communication: heighten awarencss of COPD among a broad spectrum of stakeholders and decision makers.

CDC recommends the following as it relates to the early detection of COPD: 1) Collaborate with appropriate partners to develop educational resources for people with COPD, people with COPD risk factors, families, health professionals (especially primary care providers), provider systems, media, decision makers, policy makers, and the public; and 2) Collaborate with professional health organizations to communicate current standards of diagnosis, including spirometry use, and treatment options for COPD.

CDC has done some preliminary work in the past few years, primarily surveillance and epidemiological analyses. For example, CDC in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) has: 1) developed a COPD module for the Behavioral Risk Factor Surveillance System (BRFSS), 2) conducted an analysis of the spatial trends in COPD incidence and mortality among the Medicare-eligible population, and 3) examined the trends in COPD hospitalizations, in support of the above mentioned surveillance and evaluation goal. CDC is actively working to update its COPD surveillance summary, which will be published during FY 2012 to maximize use of currently available data. CDC will continue to partner with NHLBI to support respiratory measures.

HIV/AIDS

I am concerned with the recent funding shortages in the Ryan White AIDS Drug Assistance Program (ADAP). After funding increases by the President and the Congress, the wait list

is down to 3,809 in eleven states. This is still too high and I realize that the program is growing by an average of 667 new people per month or 8,000 per year.

- **How is the Administration addressing the ADAP funding crisis to make sure people are getting their medications?**

Answer: The Administration is deeply committed to (1) reducing the number ofnew HIV infections, (2) increasing access to care and optimizing health outcomes for people living with HIV, and (3) reducing HIV-related health disparities. On December 1, 2011, President Obama announced an additional $50 million in funding for the domestic campaign to end HIV/AIDS including an additional $35 million to fund state AIDS Drug Assistance Programs (ADAPs).

The Budget targets funding to ensure that HIV-positive Americans get life-saving medications and are linked into community-based providers. This Budget has put forth an investment based on current waiting lists projections. With continued sufficient state contributions, these resources will enable all people living with HIV/AIDS who lack access to health care, to obtain life-saving medications. This is consistent with the National HIV/AIDS Strategy (NHAS), which notes that success in reaching the goals is dependent on commitments from all parts of society.

Included in the Budget is $1 billion, an increase of $67 million, for AIDS drug assistance programs to provide life saving and extending medications to 236,230 clients, an additional 18,906 people living with HIV/AIDS above FY 2012. In order to link people living with HIV/AIDS to care and remain on care, early intervention services are needed. The Budget also includes $236 million, an increase of $20 million, Ryan White for Early Intervention Programs to provide direct grants to community-based clinics that offer primary care services for HIV testing and treatment to over 265,325 patients.

The Budget also includes an increase of $40 million within CDC to support HIV prevention efforts consistent with the National HIV/AIDS Strategy. This increased funding would support implementation, data collection, and guideline development for national organizations and State and local education and health agencies to implement science-based interventions in schools settings to prevent HIV, STDs, and teen pregnancy. Funds would also be used to support health departments in their HIV prevention efforts, increase testing and decrease the risk behaviors among groups at highest risk for HIV acquisition, and improve HIV/AIDS program collaboration and service integration with prevention programs for viral hepatitis, STDs, and tuberculosis.

Interstitial Cystitis

Interstitial Cystitis (IC) is a painful bladder condition that affects at least 1 in every 77 Americans, and the IC Education and Awareness Program at tbe Centers for Disease Control and Prevention (CDC) provides assistance to these individuals. In FY12, CDC recommended defunding this program by consolidating its Center for Chronic Disease Prevention and Health Promotion. Congress restored funding for the IC program, clearly indicating our support, and yet, CDC again failed to include the program in its FY13 budget request.

- **Why was the IC program not included in the FY13 request, and what steps will CDC be taking to ensure this program continues to serve IC patients?**

Answer: The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

CDC will continue to collaborate with partners regarding appropriate public health strategies to increase awareness of interstitial cystitis. CDC will also continue to disseminate information and resources regarding interstitial cystitis to patients and providers on its website.

Psoriasis
I am pleased that the CDC has spent the last three years identifying the gaps in data on psoriasis and has developed a public health agenda as a result of Congress' fiscal year 2010 appropriation, which recognized the need for population-based data on individuals with psoriasis and psoriatic arthritis, including children and adolescents. This agenda, if implemented, could increase understanding of psoriasis, examine the relationship of psoriasis to other serious diseases, develop public health strategies to reduce the burden of diseases and prevent the onset of co-morbid conditions, and gain insight into the long-term impact of psoriasis and psoriatic arthritis.

I am deeply troubled that funding was not included to implement this psoriasis public health agenda in the President's fiscal year 2013 budget, as progress toward finding a cure will come to a standstill without continued federal investment.

- **Does the Administration plan to contribute to improved psoriasis treatment and management and further the nation's efforts to find a cure by prioritizing the psoriasis public health agenda in the future?**

Answer: As noted in your question, with previous funding, CDC consulted with the National Psoriasis Foundation (NPF) on how a public health approach to psoriasis could complement the existing clinical, research, and educational approaches to the condition. In addition, a contract was awarded to analyze and publish psoriasis surveillance data available from previously collected datasets and to develop a validation study to test a potential new surveillance system, which is to be completed in mid-2012. CDC's National Center for Health Statistics (NCHS) has

also been engaged in psoriasis work. NCHS has supported activities to analyze and publish psoriasis surveillance data available from previously collected datasets.

The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

CDC will continue to: (1) collaborate with the National Psoriasis Foundation (NPF) and other psoriatic arthritis partners regarding appropriate public health strategies to increase awareness of interstitial cystitis; and (2) support activities to analyze and publish psoriasis surveillance data. CDC will also monitor findings of studies supported by the National Institutes of Health's National Institute of Arthritis and Musculoskeletal and Skin Diseases, whose mission is to support research into the causes, treatment, and prevention of skin diseases and disseminate information on research progress in these diseases.

Prevention and Public Health Fund
According to a study by Trust for America's Health, investing $10 per person per year in proven community-based programs to increase physical activity, improve nutrition, and prevent smoking and other tobacco use, could save the country more than $16 billion annually within five years.

- **How are we using the Prevention and Public Health Fund to reduce healthcare costs?**

The Affordable Care Act included significant provisions to encourage access to clinical preventive services in Medicare, Medicaid, and private insurance.

- **In your experience as Secretary and a former insurance commissioner, have you found that insurance companies have been doing enough to promote prevention and wellness?**

Answer: HHS works closely with program area experts across the Department to identify proven activities that will have the greatest impact toward the goals of the Prevention and Public Health Fund. For example, HHS continues to support initiatives to prevent obesity and to increase immunization services and activities. These types of investments result in long-term savings.

Many insurance companies are taking important steps to promote prevention and wellness. The Affordable Care Act (ACA) is also helping Americans access important preventive services. Because of provisions within the ACA, 54 million Americans with private health insurance gained access to free recommended preventive care in 2011. Additionally, more than 32 million Medicare beneficiaries took advantage of preventive benefitswith zero cost sharing.

Community Transformation Grants
I was pleased to see new Community Transformation Grants to 61 states and localities in 2011.

- **What measures and standards are HHS and CDC using to ensure that we receive a valuable return on this investment?**
- **What specific health outcome improvement goals have been set?**

Answer: The Community Transformation Grants (CTG) program builds upon CDCs past successes and lessons learned to improve community health, and marks the next stage of CDC's commitment to community-based programs The CTG program supports states and communities to develop and implement initiatives that prevent chronic diseases, the leading causes of death and disability. CTGs focus on five strategic priority areas: 1) tobacco-free living, 2) active living and healthy eating, 3) increased use of high-impact clinical preventive services to prevent and control high blood pressure and high cholesterol, 4) social and emotional wellness, and 5) healthy and safe physical environments.

CTG awards were announced in September 2011. Sixty-one states and communities received awards. Thirty-five states and communities will implement evidence- and practice based programs designed to improve health and wellness. Twenty-six states and communities will work to build capacity to implement changes by laying a solid foundation for community prevention efforts to ensure long term success. Seven national networks of community based organizations were also funded. The four dissemination awardees will work to disseminate CTG strategies within their national network of local affiliates. The three acceleration awardees will support local communities in assessing and addressing CTG health priorities. Through this effort, more than 1 in 3 U.S. citizens are being reached, including more than 20 million Americans in rural and frontier areas.

By 2016, CTG states and communities will promote healthy lifestyles by:

- Increasing access to smoke-free or tobacco-free environments in settings such as workplaces, restaurants, and bars; multi-unit housing; schools; campuses; and outdoor places.
- Increasing access to healthy food and beverage options in schools, afterschool programs, early child care settings, workplaces, and other community settings.
- Increasing access to physical activity opportunities in schools, afterschool programs, early child care settings, workplaces, and other community settings.
- Increasing access to systems and opportunities that support control of high blood pressure and high cholesterol in health care and other community settings.

CTG grantees must align their efforts with the following program objectives:

- Reduce death and disability due to tobacco use by 5 percent in the implementation area.
- Reduce the rate of obesity through nutrition and physical activity interventions by 5 percent in the implementation area.
- Reduce death and disability due to heart disease and stroke by 5 percent in the implementation area.

The CTG program has a robust evaluation plan that includes four components:

1) Performance Monitoring to track progress on objectives and milestones, as well as the potential and actual reach of CTG strategies.
2) Population-Level Surveillance to measure changes in attitudes, risk behaviors, and other behavioral risk factors and indicators for a range of age and target population groups in select communities.
3) Cost Studies to collect and analyze cost data for funded communities aligned with the CTG Strategic Directions.
4) Enhanced Evaluation Studies to assess the actual and projected impact of specific CTG strategies on health outcomes.

National Prevention Strategy

I was pleased to see that HHS and 16 other federal agencies joined together last June to release our first ever National Prevention Strategy. In light of the obesity epidemic and the skyrocketing costs of chronic disease in this country, the strategy recognizes that we need an all hands on deck approach to prevention and wellness.

- **Can you provide an update on implementation of that strategy?**

Answer: The National Prevention Strategy released June 16, 2011, recognizes that good health comes not just from receiving quality medical care, but also from clean air and water, safe homes, worksites and neighborhoods, and healthy foods. The strategy was developed by the National Prevention Council, which is composed of 17 federal agencies who consulted with outside experts and stakeholders. Since its establishment, the National Prevention Council has met regularly and engaged stakeholders, subject matter experts, and the public to work with the presidentially appointed advisory group to identify priorities in prevention and how these can best be implemented.

The National Prevention Council is in the process of developing a federal Action Plan for the Implementation of the National Prevention Strategy. This National Prevention Council Action Plan (CAP) will represent the leadership and commitment the Council and its member Departments are making to prevention. The CAP presents Council commitments made by Council departments and describes the Department-specific efforts that align to the Federal Actions included in the National Prevention Strategy. In addition, the Council has worked to evaluate and prioritize those areas of prevention where actions taken by all of the Council members will have a high public health impact. It is likely that these cross departmental Council commitments will address achieving access to healthy affordable food and achieving tobacco-free environments.

The 2012 Annual Status Report on the work of the National Prevention, Health Promotion, and Public Health Council will be delivered to Congress and the President by July 1, 2012. HHS anticipate that this report with outline specific department actions and specific Council commitments.

Antibiotics

Given that a report card issued last October by the WMD Center gave the U.S. a grade of "F" for our ability to respond to a bioterror attack involving drug-resistant pathogens, I believe BARDA must strengthen its investment in antibiotic R&D.

- **Would the proposed increase for the Biomedical Advanced Research and Development Authority (BARDA) fund additional antibiotic R&D?**

Answer: BARDA's Broad Spectrum Antimicrobial Program is focused on developing novel antibacterial and antiviral drugs for the treatment or prevention of disease caused by currently defined and future biological threats. Recognizing the immediate value of new antimicrobials in addressing the increasingly prevalent public health threat of antibiotic resistance, as well as the likelihood that antimicrobial resistance will complicate primary treatment of a wide array of threats, BARDA is supporting the development of public-private partnerships for the development of novel antimicrobials. Through these partnerships, BARDA will support the development of candidate antimicrobials for their commercial, clinically prevalent infectious disease indications, as long as our private sector partners concomitantly support the development of these products for biodefense threat agent indications. By adopting this approach, BARDA will support the development of new classes of antimicrobials, increase the number of antimicrobial drugs in the developmental pipeline, address the important and immediate threat of antimicrobial resistance, and prepare the nation for the predictable threat of biological terrorism and the unpredictable threat of emerging infectious diseases.

More than 70 percent of the pathogens that cause healthcare associated infections (HAIs) are resistant to at least one of the antibiotics typically used to treat them. Increasing antibiotic resistance is a serious public health threat.

Question: How will the budget request strengthen the CDC's efforts with regard to surveillance of emerging resistant pathogens, collecting data on antibiotic use and resistance trends, and promoting the appropriate use of antibiotics to help slow the development of resistance?

Answer: The FY 2013 Budget will strengthen the CDC's capacity to conduct surveillance of emerging resistant pathogens, expand data collection on antibiotic use and resistance trends through the National Healthcare Safety Network (NHSN), and promote the appropriate use of antibiotics in order to slow the development of resistance. CDC will accomplish this by investing in an improved and sustainable NHSN architecture, developing and disseminating evidence-based guidelines, conducting education campaigns, and working with health departments and other partners to prevent transmission of infections and promote appropriate use of antibiotics.

National Surveillance: Tracking Trends for Antibiotic Resistance in Healthcare-associated infections (HAIs): CDC data are used to monitor resistance rates, guide prevention efforts, and evaluate the effectiveness of prevention programs; new CDC data will be used to monitor antibiotic use.

- **National Healthcare Safety Network (NHSN):** NHSN is a vital tracking tool for HAI prevention across healthcare settings. Currently 7,900 healthcare facilities report HAI data to NHSN. NHSN data are used by healthcare facilities for local improvement, and at the state and national levels to identify hotspots that require attention. Antimicrobial resistance data are reported for HAIs, and a special module is available for *Clostridium difficile* and multidrug resistant organisms, including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE).

- **Emerging Infections Programs (EIP):** To complement NHSN data, CDC conducts population-based surveillance through a network of state health departments to monitor diseases and death caused by MRSA *and carbapenem-resistant Enterobacteriaceae.*

- **Improving Antibiotic Use:** CDC is piloting an Antimicrobial Use and Resistance Module (AUR) in the NHSN. This module will allow facilities to identify areas of excessive antibiotic use and guide antibiotic stewardship interventions.

Identifying new resistant pathogens: CDC laboratories are critical in detecting and characterizing emerging resistance in the United States.

- **Reference Laboratories:** CDC laboratories provide gold-standard laboratory testing to state and local health departments, clinical laboratories, and academic researchers to detect new resistant pathogens and new mechanisms of resistance. They also conduct strain typing and molecular fingerprinting (DNA analysis) to track the spread of specific resistant pathogens.
- **Provide support to states:** CDC laboratories work with state public health laboratories to improve capacity to detect important resistance patterns.
- **Develop new diagnostic tests and methodologies for detecting resistant organisms:** When new resistance occurs, CDC assesses whether existing tests are effective. If not, CDC develops new methods and disseminates protocols so that public health and clinical labs reliably can detect new patterns and guide therapeutic decisions.

Prevention and education: CDC develops and promotes implementation of guidelines to prevent transmission of infections, and promotes appropriate use of antibiotics.

- CDC develops evidence-based infection prevention guidelines with input from the Healthcare Infection Control Practices Advisory Committee (HICPAC), providing a scientific foundation for HAI and antimicrobial (AR) prevention practices (e.g., *Management of Multidrug-Resistant Organisms in Healthcare Settings).*

- CDC conducts education campaigns promoting appropriate use of antibiotics (*Get Smart: Know When Antibiotics Work*) in physicians' offices, hospitals, and nursing homes.

CDC works with health departments and other partners to identify and eradicate newly emerging AR pathogens in specific localities or regions before they spread, promoting implementation of prompt, aggressive infection control measures in healthcare facilities.

Open Access
HHS spends tens of billions of dollars in basic and applied research each year, with the intent that this investment will accelerate the pace of biomedical discovery, and speed the development of crucial treatments, therapies, and ultimately, cures - to the public. You also invest these tax dollars with the expectation that such discoveries will help fuel the economy by spurring growth in the drug development, medical instrumentation and biotech sectors.

Access to articles reporting results of this research plays an important role in facilitating both scientific progress and economic growth.
Under HHS's leadership, the National Institutes of Health implemented a policy to require that papers reporting on its funded research are made broadly accessibly to the public, online through its PubMed Central database. With more than half a million individuals using these articles daily, the demand for this information seems clear.

- **What steps will you take to ensure that the results of research from other HHS Agencies is also made available to the public?**

Answer: HHS is actively working to encourage increased public availability of agency research results and data. In 2010, HHS and the Institute of Medicine launched the Health Data Initiative, a national initiative to help Americans understand health and health care performance in their communities. Through the website Health.Data.gov, the Initiative provides health data sets harvested from across HHS and other federal agencies. The site is continually updated as more datasets and tools become available.

In addition, HHS is a member of the Interagency Working Group on Digital Data and the Task Force on Public Access to Scholarly Publications, both of which were established under the National Science and Technology Council (NSTC) as part of the America COMPETES Reauthorization Act of 2010 (ACRA; Public Law 111-358). The Interagency Working Group on Digital Data is currently considering steps that can be taken by all relevant federal agencies to encourage and coordinate the development of agency policies and standards to promote long-term access to digital data resulting from federally-funded research. The Task Force on Public Access to Scholarly Publications has the responsibility of developing individual agency policies for ensuring public access to the results of federally-funded research, including peer-reviewed scholarly journal articles and other peer-reviewed publications.

Currently, HHS agencies other than NIH also routinely make research results available to the public. For instance, the Centers for Disease Control and Prevention's (CDC) data release policy requires that data collected by CDC using federal resources, data collected for CDC by other agencies or organizations, and data reported to CDC be released through a public-use data set as

soon as possible after they are collected, scrutinized for errors, and validated. CDC makes this data available to the public through the CDC WONDER online databases (http://wonder.cdc.gov/) and the Atlanta, Pittsburgh, and Hyattsville, MD locations of the CDC Public Health Library and Information Center.

As another example, the Agency for Healthcare Research and Quality (AHRQ) works with grantees to develop materials derived from AHRQ-funded research for specific audiences (e.g., clinicians, patients and families, health care professionals) using a variety of media and tools, and also encourages grantees to discuss any ideas about other dissemination and marketing efforts with AHRQ staff in the Office of Communications and Knowledge Transfer. In addition, AHRQ requires that final grant reports are posted in the National Technology Information Service and that grantees inform AHRQ when articles from their AHRQ-supported activities are accepted for publication in the professional literature. Furthermore, AHRQ's Effective Healthcare Program regularly posts research reviews, original research reports, and research summaries on the program's website (http://www.effectivehealthcare.ahrq.gov).

Additionally, the National Information Center on Health Services Research and Health Care Technology (NICHSR) at the National Library of Medicine, part of NIH, works closely with AHRQ to improve the dissemination of health services research results. The Health Services/Technology Assessment Text (HSTAT), one of NICHSR's products, is a free, online resource of full-text documents that provide health information and support health care decision-making. Many of the documents available through HSTAT come from HHS agencies, including: AHRQ evidence reports, guideline documents, and technology assessments; NIH Consensus Development Conference Statements and Technology Assessment Workshop Reports; HIV/AIDS Treatment Information Services (ATIS) approved guidelines (ATIS is a collaborative project sponsored by NIH, CMS, HRSA, and CDC); and SAMHSA treatment improvement protocols.

Preparedness and Response

Following Hurricane Irene, public health agencies along the eastern seaboard played a critical role in ensuring the lives and safety of their residents by safely evacuating patients from coastal facilities, opening and staffing shelters for displaced and or evacuated residents, staffing call centers with health experts to provide residents with public health information related to Hurricane Irene and subsequent flooding, and ensuring safe drinking water and food supplies after power outages.

I am concerned that the Administration's decision to combine preparedness and response activities could reduce funding for preparedness programs.

- **Are we well-enough prepared for a disaster that we can now reduce funding for core public health security programs such as Public Health Emergency Preparedness at CDC?**

- **When hospitals are the first and last line of defense in any given community when dealing with extreme casualties from a public health disaster, what is the rationale**

for cutting the Hospital Preparedness Program by $125 million, or nearly 33% FY13?

- **What is the rationale for cutting the Preparedness and Emergency Response Learning Centers program?**

Answer: Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. Initially, this funding was to support grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

The Administration is committed to cutting the deficit, restoring fiscal sustainability, and achieving better performance with the resources we have. The President's budget proposed a cut to the Preparedness and Emergency Response Learning Centers in support of this objective and so that funding could be better preserved for programs supporting public health preparedness directly in communities. The Budget also proposes a 33 percent reduction to HPP. In addition, current efforts to align preparedness grants to improve effectiveness may lead to administrative efficiencies and reduce costs to the programs. In FY 2012, the first joint funding opportunity announcement was issued for the PHEP and HPP programs; the streamlining of these grants will reduce the administrative burden and will accrue savings to the program at both the Federal and grantee levels. By enhancing cohesion between the preparedness programs, states will also be able to make more efficient use of the resources, which is imperative in a constrained budget environment.

Presently, the Department's preparedness and response activity are managed and funded separately but maintain a high degree of coordination between the two, which is vital to an effective response. The Department utilizes a variety of training exercises and working groups to ensure that preparedness planners and those engaged in disaster response share information and best practices to continuously improve our Nation's capabilities in support of all-hazards preparedness. The Department is also engaging across the healthcare spectrum of State and local actors to work with emergency medical response services, public health departments, behavior health experts, and hospitals in supporting healthcare coalitions which are ready for whole community disaster response. Viewing preparedness and response efforts under this paradigm not only enhances our Nation's response capabilities and resiliency, but also supports more effective and efficient exchange of information during a disaster.

Food Safety

Question: The rapid changes in the food supply system and the intricate farm-to-fork supply chain have created significant new responsibilities for food safety protection programs. In addition to a shrinking pool of trained food safety personnel, the economic downturn has forced many state and local agencies to lay off staff, causing additional strain on states' abilities to protect the nation's food supply. It is estimated that one in six people living in the United States is sickened by foodborne diseases each year, resulting in an estimated 128,000 hospitalizations and 3,000 deaths at an annual cost of $152 billion.

- **What are the challenges of keeping our food supply safe?**

Answer: Keeping the U.S. food supply safe is a complex challenge. Today's food safety system must meet the demands of a food supply system vastly different from 100 years ago, or even 10 years ago. Our food supply is truly global -- 15 percent of food overall is imported. When you look at specific commodities, the percentages are even greater – approximately 75 percent of seafood is imported; approximately 20 percent of vegetables is imported; and approximately 50 percent of fruit is imported.

Our food supply is more technologically advanced and complex, allowing foods to travel longer distances and be held in ready-to-eat form for longer periods of time. There are new hazards: new pathogens are emerging and old pathogens are turning up in foods in which they had not been previously identified. In addition, as the demographics of our country change, there is a larger percentage (about 30 percent) of people at increased risk for foodborne illness.

It is these challenges and the persistent occurrence of foodborne outbreaks that inspired Congress to enact the FDA Food Safety Modernization Act (FSMA). The preventive controls framework envisioned in FSMA is a significant tool for modernizing our food safety system to meet the challenges of today's food supply.

We are all familiar with the Listeria outbreak due to contaminated cantaloupes last year.

- **What would be the consequences if we lost federal funding for food safety surveillance and response in such a situation as a food borne disease outbreak?**

Answer: The consequences of loss of federal funding for food safety surveillance and response would be far reaching. Recent efforts to streamline and enhance surveillance activities on the part of FDA and the Centers for Disease Control and Prevention (CDC) would be greatly curtailed, and our ability to react quickly to a foodborne disease outbreak, such as the Listeria illnesses and deaths linked to whole cantaloupe, would be severely hampered. Tracing an outbreak to its source would be more difficult. Frequently there may be multiple common products identified and multiple points of service involved in an outbreak.

Product traceback activities are very resource-intensive. Currently, FDA and CDC work together to determine the cause of an outbreak, tracing records and sources back through the supply chain and making sure that potentially contaminated product is removed from the marketplace and no longer poses a threat to consumers. Loss of funding could lead to a slower identification of the pathogen causing the illnesses and identification of the contaminated food product. The interaction of FDA, CDC, the US Department of Agriculture, and state and local public health officials, as well as the affected industry, is crucial in this endeavor. The ability to follow up at the source of an outbreak and identify what practices may have led to the contamination is essential to inform future prevention activities and to serve as the basis of outreach to industry in an effort to provide more immediate guidance.

Surveillance activities and trending the data also allow FDA to gauge the effectiveness of current food safety initiatives in order to develop and plan future activities to prevent and/or reduce foodborne illnesses.

Preventive Health and Health Services Block Grant
For more than 30 years state and local health departments have relied up the flexibility of the Preventive Health and Health Services Block Grant to address their unique local solutions for a wide variety problems and needs. We are seeing state support for hospital and emergency preparedness being cut in this budget, and also the complete elimination of the CDC Prevention Block Grant.

- **What impact will these proposed cuts have on the basic public health protection of our nation?**

Answer: Through CDC's existing and expanding activities, there is substantial funding to state health departments to address community health needs. The activities currently supported by the Preventive Health and Health Services Block Grant may be more effectively and efficiently implemented through the new Coordinated Chronic Disease Prevention and Health Promotion Grant. The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.
Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. This funding has supported grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

Section 317
The CDC would take one of the largest hits in the budget request, and especially concerning is the proposed reduction in the 317 immunization program. A report to this Committee from CDC estimates that this program is underfunded by hundreds of millions of dollars. Even with expanded coverage of the Affordable Care Act in 2014, over 20 million people will still be without insurance. Vaccination programs have been proven to be some of the most cost-effective approaches to preventing disease and reducing healthcare costs, and the children's vaccine programs are estimated to be a 10:1 savings as one example. The 317 program provides the infrastructure for the Vaccines for Children program, which has been a huge success.

- **What is the rationale for cutting this program by $58 million or close to 10% when we are still one to two years away from expanded coverage?**

Answer: The FY 2013 Budget includes funds for vaccine purchase to continue outreach to the hardest to serve populations, and critical immunization operations and infrastructure that supports national, state, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs $25 million towards continuation of the billables project, which allows public health departments to vaccinate and bill for fully-insured individuals in order to maintain Section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The FY 2013 Budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The Budget does not continue funding for one-time enhancements planned for FY 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan. Health reform expansion will further increase access to immunizations and decrease the number of uninsured and underinsured individuals served by the Section 317 Program, resulting in cost savings.

Questions for the Record for Secretary Kathleen Sebelius
Submitted by Rep. Lucille Roybal-Allard

CDC Chronic Disease Center Consolidation and Diabetes Programs

The FY 2013 HHS budget request for the Coordinated Chronic Disease Prevention and Health Promotion Program states that it provides an increase of $128.699 million. The HHS budget estimates that this increased funding will allow CDC to increase the average awards to states from approximately $2.6 million to approximately $4.5 million.

Questions:

1. **What formula did you use to calculate the increased average awards for states?**

Answer: The Coordinated Chronic Disease Prevention and Health Promotion Program formula component for state awards will be based on a combination of population size and disease burden. "Disease burden" is represented by percent of the population at or below 200% of the federal poverty level, which correlates closely with rates of several of the leading chronic diseases and conditions, as well as risk factors.

2. **While every state has a diabetes program, not every state has a heart disease, arthritis, school health, or obesity program. Does the funding in the consolidation to ensure that states have adequate resources to address all chronic diseases included in the proposed consolidation?**

Answer: Chronic diseases – such as heart disease, stroke, cancer, diabetes, and arthritis – are among the most common, costly, and preventable of all health problems in the United States. Historically, CDC has funded categorical programs in state health departments to address these diseases as well as their common risk factors of obesity, poor nutrition and/or inadequate physical activity. Under the current structure, not all states are funded for these programs.

The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. The proposed FY 2013 CCDPHPP will increase the average awards to states from approximately $2.6 million to approximately $4.5 million. This increase in funding will permit states, tribes, and territories to support a broader range of programs targeting the leading causes of chronic disease-related death and disability and their associated risk factors. Within the total program level, no more than 20 percent of total funding will be allocated to program administrative costs, including CDC's technical assistance, evaluation, oversight, and management activities.

This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

The Division of Diabetes Translation (DDT) at CDC is doing excellent work to address the diabetes epidemic, including translating research into better prevention and care, enhancing the state Diabetes Prevention and Control Programs, supporting the National Diabetes Education Program, and expanding diabetes surveillance.

Questions:

3. **Would you please explain how, under the proposed consolidation of the Chronic Disease Center, resources at the state and national level would be maximized to improve and enhance prevention efforts for individuals with or at risk for diabetes?**

Answer: Chronic diseases – such as heart disease, stroke, cancer, diabetes, and arthritis – are among the most common, costly, and preventable of all health problems in the U.S. Historically, CDC has funded categorical programs in state health departments to address these diseases as well as their common risk factors of obesity, poor nutrition and/or inadequate physical activity. Under the current structure, not all states are funded for these programs. In order to maximize the reach and impact of every dollar invested by CDC, the Coordinated Chronic Disease Prevention and Health Promotion Program (CCDPHPP) consolidates several existing programs that address common risk factors (e.g., physical inactivity and nutrition): heart disease and stroke, obesity, diabetes, arthritis and other conditions, comprehensive cancer, obesity prevention, health promotion and school health activities.

The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. The proposed FY 2013 CCDPHPP will increase the average awards to states from approximately $2.6 million to approximately $4.5 million. This increase in funding will permit states, tribes, and territories to support a broader range of programs targeting the leading causes of chronic disease-related death and disability and their associated risk factors.

This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. Individuals with diabetes are at a much greater risk for other chronic conditions and disability, such as heart disease, vision loss, and amputations. Therefore, coordination of all chronic disease programs will ensure that efforts to prevent and reduce the effects of diabetes among at-risk populations will be at their most effective. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

4. Would you please tell me specifically how the Coordinated Chronic Disease Prevention and Health Promotion Program will be structured and how the funding for the components of the consolidation will operate?

Answer: In FY 2013, funding will support:

- Core, formula-based awards to state, tribal, and territorial health departments based on population size and chronic disease burden;
- Additional competitive awards to state, tribal, and territorial health departments for specific chronic disease interventions, including 1) strategies that support and reinforce healthful behaviors and expand access to healthy choices; 2) health systems interventions to improve the delivery and use of clinical and other preventive services, such as blood pressure control, appropriate aspirin use, and cancer screenings; and 3) community-clinical linkage enhancement to better support chronic disease self-management;
- Competitive awards to national organizations, national networks, and other entities to disseminate best practices and effective interventions; and
- Performance incentives for states, tribes, and territories that are able to meet targeted performance measures associated with the CCDPHPP competitive awards.

CDC Diabetes Programs

In FY12 the National Diabetes Prevention Program (NDPP) received $10 million in funding for the first time. The NDPP works to reduce the rising epidemic of type 2 diabetes by ensuring the availability of low-cost, highly successful diabetes prevention programs in

local communities across the country. However, the NDPP was not specifically included in the FY 2013 budget.

Questions:

5. **When will FY 2012 NDPP funding become available?**

Answer: CDC established the National Diabetes Prevention Program in 2010 to reach individuals at greatest risk for type 2 diabetes. Implementation of the program is continuing through actions around four program levers: training, program recognition, intervention sites and health marketing. Inaugural partners of the National Diabetes Prevention Program were CDC, the YMCA of the USA and United Health Group (UHG). Currently, the National Diabetes Prevention Program is available in 41 sites that include 34 CDC funded sites and 7 United Health Group supported sites in YMCAs across the country.

In FY 2012, CDC will announce a new funding opportunity entitled "Preventing Type 2 Diabetes Among People at High Risk". The purpose of this program is to support organizations to deliver and sustain evidence-based lifestyle change programs that have proven to prevent the onset of diabetes for individuals with pre-diabetes. Organizations must have an established network with national, regional, state or local reach. The Diabetes Prevention Recognition Program (DPRP) is a critical component of the National Diabetes Prevention Program. This program provides recognition to faith-based organizations, community health organizations, government entities and others seeking to be a part of the National Diabetes Prevention Program and have the infrastructure best suited to deliver evidence-based type 2 diabetes interventions. CDC recognition will assure quality of the program for insurers with an interest in paying for evidence-based diabetes prevention programs in a scalable and sustainable manner, maximize the public health benefit, and model the health and economic utility of this approach for third-party payers. Awards to organizations for the National Diabetes Prevention Program funding opportunity announcement will be awarded by September 30, 2012.

The National Diabetes Prevention Program estimates reaching approximately 115,000 high risk individuals with pre-diabetes with the evidence-based type 2 diabetes prevention lifestyle intervention. In the coming years, these figures are expected to increase exponentially as enhancements to infrastructure occur, program participation grows, and private insurer reimbursement systems are established to sustain the program.

6. **What is your plan for ensuring the NDPP has adequate resources in FY 2013 to continue to expand?**

Answer: CDC anticipates continued support of the National Diabetes Prevention Program through the new Coordinated Chronic Disease Program . These activities will lay the groundwork for long-term sustainability. The NDPP will become a sustainable part of the health care system as community providers of diabetes prevention are recognized and deliver expected health outcomes, and as public and private payers reimburse these community providers for their services.

Health Workforce Diversity Programs
Last year HHS released two strategic plans to reduce health disparities in this country. Included in these plans was the need to increase the proportion of minorities working in the health professions.

Question:

1. **One of the successful programs for building a minority pipeline for the health professions is the Health Careers Opportunity Program (HCOP). Why did your budget proposal contain no support for this proven program?**

Answer: The President's Budget prioritizes funding activities that have a more direct impact on expanding the primary care workforce by supporting students who have committed to and are training as health professionals. Investments initiated in the FY 2013 Budget will train an additional 2,800 primary care providers over the next 5 years.

Other federally-funded health workforce development workforce programs will continue to promote training of individuals from disadvantaged backgrounds and increase the likelihood that disadvantaged students are able to attend health professions programs through recruitment activities and scholarship opportunities. For example, the FY 2013 Budget includes $22.9 million for the Centers of Excellence program to recruit, train, and retain underrepresented minority students and faculty in health care fields to increase the supply and quality of underrepresented minorities in the health professions. In addition, the FY 2013 Budget includes $47.5 million for the Scholarships for Disadvantaged Students Program which provides grants to health professions and nursing schools for use in awarding scholarships to financially needy students from disadvantaged backgrounds. This program aims to increase the diversity of the health professions workforce as well as to increase the number of primary care providers working in medically underserved areas.

Increasing the diversity of the health professions workforce is an area of focus for HRSA's health professions programs and for the most recent academic year, 58 percent of the graduates from HRSA-funded programs were disadvantaged and/or underrepresented minorities (URM). Similarly, the proportion of National Health Service Corps Scholarship Program participants who are underrepresented minorities exceeds the average national enrollment rates for URMs in health professions disciplines. Other examples of programs that support diversity in the health professions workforce are the Primary Care Training and Enhancement and the Nursing Workforce Diversity programs. Grantees in the Primary Care Training and Enhancement program must put a plan in place to increase the number of diverse health professionals and must document their progress. Grantees under the Nursing Workforce Diversity program work to increase educational opportunities for disadvantaged individuals pursuing nursing degrees.

The Area Health Education Center (AHEC) program also receives no funding in the FY13 budget proposal. Ironically, just one year ago, the administration requested an increase in funding for this important program, and said AHECs play a critical national role in addressing healthcare workforce shortages. The budget justification explains this reduction by stating that the funding allocations for training are being focused on

programs that have a direct link to a training program for a primary health care professional. Just last year the budget justification correctly described the program by stating that the AHEC grantees support the recruitment and retention of physicians, students, faculty, and other primary care providers in rural and medically underserved areas by providing local, community-based, interdisciplinary primary care training.

Answer: The Budget targets funding to activities that directly increase the capacity of the health workforce. The Budget focuses on activities that more directly impact the overall supply of health professionals. All AHEC grants require both a plan of self-sufficiency and a 50% non-Federal match. Grantees' self-sufficiency plans require the specification of other sources of income and a timetable for becoming autonomous.

Other federally-funded health workforce development workforce programs will continue to promote training of individuals from disadvantaged backgrounds and increase the likelihood that disadvantaged students are able to attend health professions programs through recruitment activities and scholarship opportunities. For example, the FY 2013 Budget includes $22.9 million for the Centers of Excellence program to recruit, train, and retain underrepresented minority students and faculty in health care fields to increase the supply and quality of underrepresented minorities in the health professions. In addition, the FY 2013 Budget includes $47.5 million for the Scholarships for Disadvantaged Students Program which provides grants to health professions and nursing schools for use in awarding scholarships to financially needy students from disadvantaged backgrounds. This program aims to increase the diversity of the health professions workforce as well as to increase the number of primary care providers working in medically underserved areas.

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Question:

2. **Please explain the turnaround in administrative support for the AHEC program that has clearly excelled in training primary care professionals?**

Answer: The FY 2013 President's Budget prioritizes allocating federal resources to training programs that directly increase the number of primary care providers. While HRSA has made longstanding investments in these activities to enhance health professions training since 1972, they do not directly increase the supply of providers. Given that most AHEC programs have

been in place for many years and have state and local support, it is anticipated that the AHEC Program grantees will continue much of their efforts relying on these other funding sources.

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3. Shouldn't we be investing in a program that not only trains the primary care workforce, but recruits and prepares the future healthcare workforce as well?

Answer: A number of HRSA programs support recruitment activities such as scholarship and loan repayment that allow health professions students the opportunity to become the future health professions providers. The budget includes $383 million for HRSA's National Health Service Corps Scholarship, Nursing Scholarship and National Health Service Corps Students to Service Loan Repayment, to build the pipeline of future primary care providers by removing the burden of significant education debt. These Programs require service in underserved communities or facilities, offering quality health care to underserved communities that need it while adequately preparing the health care workforce for the health needs of the nation.

Another example of a federally-funded health workforce development workforce program that supports recruitment activities is the Centers of Excellence program which funds activities to recruit, train, and retain underrepresented minority students and faculty to increase the supply and quality of underrepresented minorities in the health professions. The Scholarships for Disadvantaged Students Program, which is funded at $47.5 million in FY 2013, promotes

increased diversity in the health professions workforce as well as to increasing the number of primary care providers working in medically underserved areas.

Community Health Centers
The FY13 HHS budget calls for adding only 25 new health centers nationwide in FY13, despite the additional $1.5 billion mandated by the ACA for health center expansion this year.

Questions:
1. **Is it true that there are more than 1800 applications currently pending at HRSA for health center expansion?**

Answer: In FY 2011, HRSA received 1,096 expanded medical capacity applications and 880 service expansion applications. These health center applications remain viable for one year. In FY 2012, HHS anticipates that up to $145 million will be available to support approximately 220 new access points grants. The funding will support the FY 2011 approved but unfunded applications following the rank order list consistent with statutory health center requirements to make awards for FY 2012. The FY 2011 applicants will be required to submit information in March to verify continued eligibility for a New Access Point award. HHS anticipates making awards in June or July 2012.

2. **If we will only be adding 25 new health centers each year, will we have the primary care capacity to serve the millions of new consumers across the country who will be added to Medicaid in 2014?**

Answer: Health centers will continue to be a critical element of the health system as the United States expands insurance coverage through the Affordable Care Act, largely because they can provide an accessible and dependable source of primary care services in underserved communities. As such, the long-term strategy for Health Centers takes into account the need to open new health centers in areas in the country where they do not currently exist. The Budget will enable health centers to continue to provide critical access and services to millions of Americans in FY 2013 and for many years to come.

In FY 2012, HHS/HRSA plans to make approximately $145 million available to establish approximately 220 health center new access points across the country. These grants will support new full-time service delivery sites for the provision of comprehensive primary and preventive health care services to approximately one million additional patients. In FY 2013, $19 million is proposed for awards to establish approximately 25 new health center access points to support new full-time service delivery sites for the provision of comprehensive primary and preventive health care services to approximately 150,000 additional people.

The FY 2013 Budget Request promotes a long-term strategy to manage the mandatory funding appropriated to Health Centers through Section 10503 of the Affordable Care Act. This strategy will promote steady and sustainable Health Center growth beyond after FY 2015, when ACA mandatory funding is no longer available. In FY 2013, $280 million will be reserved for future

fiscal years to sustain health center funding and ensure that current health centers can continue to provide essential health care services to their patient populations.

NIDDK Budget

In the proposed FY 2013 HHS budget, the NIDDK received a slight decrease in funding of $2 million compared with the FY 2012 funding level.

Questions:

1. **Would you please share with us the percentage of grants that NIDDK has been able to fund over the past two years and how this cut will affect grants/research going forward?**

2. **Would you please provide me with a list of the specific research initiatives or projects NIDDK or other institutes at NIH are currently funding to address gestational diabetes, a disease affecting up to 18% of all pregnant women that has long-term health consequences face women and children?**

Answer: To your first question, in FY 2010 and 2011, the success rates for NIDDK-funded new and competing research project grants (RPGs) were 26% and 21%, respectively; the estimate for FY 2012 is 20%. In the FY 2013 President's Budget request, there is an overall reduction of 1% in the average cost of both competing and non-competing RPGs. As a result, the number of new and competing RPGs would increase by 43, resulting in an estimated success rate of 21% in FY 2013, even though, under the request, NIDDK would receive a slight decrease in funding of $2.8 million compared with FY 2012.

To your second question, as the number of overweight and obese pregnant women continues to rise in the U.S., gestational diabetes mellitus (GDM) is similarly rising. NIDDK and NICHD are investing in research studies and other efforts to address GDM and its immediate and long-term health consequences for women and their children. While complete data for FY 2012 are not yet available, I can highlight a number of current efforts. Under its "Healthy Pregnancy Program," NIDDK is supporting three major GDM-related initiatives:

- A multi-center research consortium that is testing interventions in diverse groups of overweight and obese pregnant women to improve weight and metabolic outcomes in both the women and their offspring. This effort is co-supported by NICHD, NHLBI, and the Office of Research on Women's Health.
- The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) Follow-up Study, which will be funded this spring to examine whether elevated blood sugar levels less severe than GDM carry similar long-term health risks for women and their offspring.
- An educational component, led by the National Diabetes Education Program (a joint program of the NIDDK and the CDC), that targets women with a history of GDM, their families, and health care providers to raise awareness of health risks and the steps that women and their children can take to avert health problems.

NIDDK and NICHD are also supporting basic and clinical studies to better understand GDM and to find ways to prevent or treat it and its long-term health risks. Many studies are focused on

understanding exactly how maternal diet and metabolism affect fetal development and incur long-term risks for obesity and other health problems. Scientists also continue to study women at risk for type 2 diabetes due to GDM history who participated in the landmark Diabetes Prevention Program. Researchers are also:

- Searching for abnormalities in fetal development of heart function and other factors that could eventually cause adult heart disease in offspring of pregnant laboratory animals with GDM.
- Analyzing post-partum maternal and infant cord blood samples to determine whether specialized types of human fat and immune cells could be a novel biochemical marker for future GDM;
- Following a large population of women who have had GDM to understand how the frequency and duration of their breastfeeding may prevent their later development of type 2 diabetes; and
- Screening women for GDM in the first months of pregnancy, to understand whether early-emerging and later-emerging forms of GDM differentially affect maternal and child outcomes. Other goals are refining GDM tests and determining, at a systems level, whether routine screening for early GDM in obese women improves their and their children's outcomes.

Alzheimer's Disease

In 2010, Congress passed the National Alzheimer's Project Act requiring the creation of a national strategic plan to address the rapidly escalating Alzheimer's disease crisis.

Questions:

1. **Can you discuss the planning efforts on Alzheimer's disease currently underway by the Administration as mandated by the National Alzheimer's Project Act?**

Answer: In April 2011, HHS established an Interagency Group on Alzheimer's Disease and Related Dementias to begin carrying out the National Alzheimer's Project Act.

This Interagency Group includes the Department of Veterans Affairs, the National Science Foundation, and the Department of Defense, as well as HHS representatives from the Office of the Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Health, NIH's National Institute on Aging, Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention, Administration on Aging, Health Resources and Services Administration, Agency for Healthcare Research and Quality, Substance Abuse and Mental Health Services Administration, Food and Drug Administration, Indian Health Service, and Administration for Children and Families.

The Interagency Group is divided into three subcommittees that inventoried all federal programs in each category of research, clinical care, and services. These inventories were then used to identify areas of overlap and opportunities for collaboration, as well as an analysis of gaps. The inventory and gap analysis formed the basis for the Framework for the National Plan to Address Alzheimer's Disease, which was released on January 10, 2012.

In May 2011, HHS created the Advisory Council on Alzheimer's Research, Care, and Services. This group includes 12 members who have expertise in Alzheimer's disease and represent major stakeholder groups and 15 members who work in Federal agencies. This Advisory Council met for the first time in September 2011. At the January 17-18 meeting, the Advisory Council provided feedback on the Framework for the National Plan and suggestions for priority action steps to achieve the goals identified in the Framework.

On February 22, 2012, the Draft National Plan to Address Alzheimer's Disease was released. HHS accepted comments on this Draft National Plan until March 30. A telephonic meeting of the Advisory Council was held on March 14. During this time, the Advisory Council made recommendations on the Draft National Plan. A Second Draft National Plan to Address Alzheimer's Disease will be shared with the Advisory Council prior to an April 17 in-person meeting. The National Plan to Address Alzheimer's Disease is expected to be released in early May.

2. How does the FY13 budget aim to eliminate the national burden of Alzheimer's by 2025?

Answer: On February 7, 2012 HHS announced the Administration's investment in Alzheimer's disease. In FY 2012, $56 million was immediately invested in additional Alzheimer's disease activities. The National Institutes of Health (NIH) dedicated an additional $50 million to Alzheimer's research. NIH investments will include research to identify genes that increase the risk of Alzheimer's disease and testing therapies in individuals at the highest risk for the disease.

In FY 2012, HHS also put $6 million from the Prevention and Public Health Fund toward the healthcare provider outreach and education initiative and a public awareness and education initiative. These efforts, which continue into FY 2013, are described in detail below.

The FY 2013 budget seeks to support the elimination of the burden of Alzheimer's disease by 2025 through an additional $100 million investment in key areas funded from the Prevention and Public Health Fund.

Research: The FY 2013 Budget includes $80 million in new Alzheimer's research funding within the Prevention and Public Health Fund allocation. Priorities for areas of research will be shaped, in part, by the Alzheimer's Disease Research Summit that will be held by the National Institutes of Health on May 14 and 15. This investment builds on an additional $50 million for Alzheimer's research dedicated by NIH from its FY 2012 funds. The FY 2012 investments will include research to identify genes that increase the risk of Alzheimer's disease and testing therapies in individuals at the highest risk for the disease. This FY 2013 funding from the Prevention Fund is in addition to the $449 million that NIH estimates it would spend on Alzheimer's disease research under the FY 2013 NIH budget request.

Support of Informal Caregivers for Persons with Alzheimer's: $10.5 million from the Prevention Fund to be used by the Administration on Aging (AoA) to support informal caregivers by building and strengthening the dementia capability a number of states, tribal entities, or large localities.

Healthcare Provider Outreach and Education: $4 million from the Prevention Fund to be used by the Health Resources and Services Administration (HRSA) to expand the Geriatric Education Centers (GEC) program. The GECs will develop curricula for trainings on Alzheimer's and dementia, provide these trainings free-of-charge as continuing education to providers, and provide videos or audio files of the trainings for distribution on a centralized website so that others who were not able to attend may receive the training.

Public Awareness and Education: $4.2 million from the Prevention Fund to be used by AoA to design and carry out a comprehensive awareness, outreach, and education initiative on Alzheimer's disease slated to begin in 2012.

Data Improvements: $1.3 million from the Prevention Fund to the Office of the Assistant Secretary for Planning and Evaluation (ASPE) to develop, test, and field a survey supplement on care for people with Alzheimer's disease. ASPE will solicit the input of the Advisory Council and federal policymakers and researchers to identify the major policy research questions related to Alzheimer's disease that remain unanswered and use this investment to make data improvements necessary to address these questions.

3. How is the Administration coordinating federal efforts and evaluating existing programs?

Answer: Since April 2011, HHS has been convening the Interagency Group on Alzheimer's Disease and Related Dementias. This Interagency Group includes the Department of Veterans Affairs, the National Science Foundation, and the Department of Defense, as well as HHS representatives from the Office of the Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Health, National Institute on Aging, Centers for Medicare and Medicaid Services, Centers for Disease Control, Administration on Aging, Health Resources and Services Administration, Agency for Healthcare Research and Quality, Substance Abuse and Mental Health Services Administration, Food and Drug Administration, Indian Health Service, and Administration for Children and Families.

Through its convening, the group has improved its coordination efforts. The Interagency Group also formed three subcommittees that inventoried all federal programs in each category of research, clinical care, and services. These inventories were then used to evaluate areas of overlap, opportunities for collaboration, and gaps.

4. When should we expect to see the first National Alzheimer's Plan and the recommendations of the Advisory Council on Alzheimer's Research, Care, and Services transmitted to Congress?

Answer: The first National Alzheimer's Plan and the recommendations of the Advisory Council on Alzheimer's Research, Care, and Services are expected to be transmitted to Congress in the summer of 2012.

5. What is HHS currently doing to ensure providers understand Alzheimer's disease and that people living with Alzheimer's and their families are receiving the best quality of

care possible? How do you plan to involve stakeholders in this process and disseminate best practices?

Answer: The Draft National Plan to Address Alzheimer's Disease includes one goal that specifically addresses these issues: *Goal 2: Enhance Care Quality and Efficiency.*

Under Goal 2, some of the actions that HHS commits to carrying out relate to building a workforce with the skills to provide high-quality care by educating healthcare providers about Alzheimer's disease (Action 2.A.1); encouraging providers to pursue careers in geriatric specialties (Action 2.A.2); and collecting and disseminating dementia-specific guidelines for provider groups (2.A.3). HHS seeks to improve the care that people receive by identifying and disseminating appropriate assessment tools (Action 2.B.2); educating providers about linking patients with services and supports (Action 2.C.1); identifying dementia care guidelines and measures for a variety of care settings (Action 2.D.1); examining new models of care for people with Alzheimer's (Actions 2.E.1 and 2.E.2); and improving care transitions (2.F.2).

A key component of this National Plan will be the partnership between the government and the private sector. HHS has already identified outside groups to partner with on these efforts and will continue to seek partnerships as the Plan is implemented. Best practices will be disseminated through these partner organizations, as well as the Aging Network, public health network, and other relevant provider networks.

The President's FY2013 Budget for CDC cuts funding for state and local Public Health Emergency Preparedness (PHEP) Cooperative Agreements by $8 million to absorb an elimination of CDC's operating costs for this program. These PHEP grants have been cut by 28 percent since FY2004.

Question:

1. **Given the storms that hit the Midwest over the last week and the fires and landslides experienced each year in California, how will the Administration ensure that communities are prepared for all hazards they may face in light of this reduction?**

Answer: Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. Initially, this funding was to support grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

The Administration is committed to cutting the deficit, restoring fiscal sustainability, and achieving better performance with the resources we have. Current efforts to align preparedness grants to improve effectiveness may lead to administrative efficiencies and reduce costs to the programs. In FY 2012, the first joint funding opportunity announcement was issued for the PHEP and HPP programs; the streamlining of these grants will reduce the administrative burden and will accrue savings to the program at both the Federal and grantee levels. By enhancing

cohesion between the preparedness programs, states will also be able to make more efficient use of the resources, which is imperative in a constrained budget environment.

The Department also utilizes a variety of training exercises and working groups to ensure that preparedness planners and those engaged in disaster response share information and best practices to continuously improve our Nation's capabilities in support of all-hazards preparedness. The Department is also engaging across the healthcare spectrum of State and local actors to work with emergency medical response services, public health departments, behavior health experts, and hospitals in supporting healthcare coalitions which are ready for whole community disaster response. Viewing preparedness and response efforts under this paradigm not only enhances our Nation's response capabilities and resiliency, but also supports more effective and efficient exchange of information during a disaster.

Community Transformation Grants
The Community Transformation Grants at CDC are cut by $81 million in the President's FY2013 Budget.

Questions:

1. **How does the Administration propose to make an impact on chronic disease rates with a one-time increase in funding?**

Answer: Plans for the 2012 increase in CTG funds are currently under development.

2. **Does the Administration support local and state health department eligibility for these grants, as per the underlying authorization in the Affordable Care Act?**

Answer: State and local health departments were eligible to compete for the 2011 CTG program. CDC supports the eligibility of a range of governmental and non-governmental agencies and organizations from across multiple sectors to engage in the work of community health promotion. CDC supports chronic disease prevention in communities through evidence-based programs, such as CTG. Local and state health departments are closely attuned to the health-related needs and challenges of their residents and play a critical role in improving the health of our nation. CDC has a lengthy history of partnering with local and state health departments and plans to continue to foster these partnerships.

School Based Healtb Centers
School-based health centers (SBHCs) are a vital safety net provider for our school-aged children across the country. Despite the fact that the administration has previously supported this program, SBHCs did not receive specific funding in your FY 2013 budget.

Questions:

1. **How will HHS encourage SBHCs in FY2013?**

Answer: The Affordable Care Act appropriated $200 million from FY 2010 – 2013 to address capital needs, including new construction, alteration/renovations and equipment-only projects, to improve delivery and support expansion of services at school-based health centers. While funds

have only been provided for the capital grants, experience has demonstrated that capital funding can significantly expand service delivery. In addition, SBHCs may apply for ACA appropriated Health Center New Access Point funding to support new health care service delivery sites, if they meet the Health Center Program eligibility criteria. HRSA will continue to offer technical assistance to communities interested in developing partnerships and formal affiliations that support the provision of primary health care to underserved populations, including school-aged children.

2. **Can you offer some examples on how you will support FQHC's looking to form partnerships with school districts and local health departments that currently operate school-based health centers within the service area of the community health center?**

Answer: HRSA currently funds a cooperative agreement with the National Assembly on School-Based Health Care (NASBHC). The goal of the cooperative agreement is to advance the sustainability and long-term growth of SBHCs by building key national, state, and local partnerships. Utilizing web-based resources and trainings, telephone and direct onsite consultation, and education programs in national, state and regional venues, NASBHC provides technical assistance to health center programs to meet the start-up, planning, and ongoing operational needs of their sponsored SBHCs. This is one example of how HRSA will continue to offer technical assistance to communities interested in developing partnerships and formal affiliations that support the provision of primary health care to underserved populations, including school-aged children.

3. **Will HHS be offering priority to applications for new access points and expanded medical capacity to those providers that sponsor SBHCs?**

Answer: The Affordable Care Act appropriated $200 million from FY 2010 – 2013 to address capital needs, including new construction, alteration/renovations and equipment-only projects, to improve delivery and support expansion of services at school-based health centers. While funds have only been provided for the capital grants, experience has demonstrated that capital funding can significantly expand service delivery. In addition, SBHCs may apply for ACA appropriated Health Center New Access Point funding to support new health care service delivery sites, if they meet the Health Center Program eligibility criteria. HRSA will continue to offer technical assistance to communities interested in developing partnerships and formal affiliations that support the provision of primary health care to underserved populations, including school-aged children.

Public Health Service Corps
The ACA provides for a public health science track that would support 850 students who would ultimately join the Commission Corps.

Questions:
1. **Have you requested any funding for this program in your budget requests? If so, how much? If not, why not?**
2. **How many people currently serve in the United State Public Health Service Corps?**

3. **How does that number compare to 10 years ago or 5 years ago? If it is less, what programs or services have you had to reduce?**
4. **How many Corps members do you need?**
5. **How many will be retiring in the next 5 years and how do you recruit for the Corps?**

Answer: Section 274 of the Affordable Care Act states that, "Beginning with fiscal year 2010, the Secretary shall transfer from the Public Health and Social Services Emergency Fund such sums as may be necessary to carry out this part." Subsequently, section 1828 of Public Law 112-10 (signed April 15, 2011 – entitled Department of Defense Full-Year Continuing Appropriations Act) states, "Hereafter, no funds appropriated by this division or by any previous or subsequent Act shall be available for transfer under section 274 of the PHS Act." This statutory language prohibits HHS from transferring funds to support this program, and subsequently HHS has not requested future funding.

Currently, the force strength of the U.S. Public Health Service Commissioned Corps (Corps) is 6,594 officers. Comparatively the Corps had 5,631 officers in 2002 and 5,909 officers in 2007. Corps officers are funded by the agencies and departments that employ them. The desired end strength of the Corps is principally determined by the needs of the customer agencies and departments and their ability to fund officers.

In the next five years, 2,392 officers will be eligible for retirement, of these, 365 will reach their mandatory 30-year retirement date (over the last five years, on average, the Corps has retired just over 200 officers per year). Corps centralized recruitment focuses on specific, difficult to recruit/retain professions that are needed to fulfill the Corps' mission to serve vulnerable and underserved populations in hard to fill and remote assignments. Recruitment of Corps Officers is also supplemented by customer agencies recruitment efforts as determined by the needs of the agency.

AIDS Drug Assistance Program
Last September, there were 9,298 people on waiting lists for HIV/AIDS medications. Currently, after some funding increases by the President and the Congress, the wait list is down to 3,809 in eleven states, however, this is still too high when the program is growing by an average of 667 new people per month or 8,000 per year.

Question:
1. **How is the Administration addressing the ADAP funding crisis to make sure people are getting their medications?**

Answer: The Administration is deeply committed to (1) reducing the number of new HIV infections , (2) increasing access to care and optimizing health outcomes for people living with HIV, and (3) reducing HIV-related health disparities. On December 1, 2011, President Obama announced an additional $50 million in funding for the domestic campaign to end HIV/AIDS including an additional $35 million to fund state AIDS Drug Assistance Programs (ADAPs).

The Budget targets funding to ensure that HIV-positive Americans get life-saving medications and are linked into community-based providers. This Budget has put forth an investment based

on current waiting lists projections and with continued sufficient state contributions, these resources will enable all people living with HIV/AIDS who lack access to health care to obtain life-saving medications. This is consistent with the National HIV/AIDS Strategy (NHAS), which notes that success in reaching the goals is dependent on commitments from all parts of society.

Included in the Budget is $1 billion, an increase of $67 million, for AIDS drug assistance programs to provide life saving and extending medications to 236,230 clients, an additional 18,906 people living with HIV/AIDS above FY 2012. In order to link people living with HIV/AIDS to care and remain on care, early intervention services are needed. The Budget also includes $236 million, an increase of $20 million, for Ryan White Early Intervention Programs to provide direct grants to community-based clinics that offer primary care services for HIV testing and treatment to over 265,325 patients.

The Budget also includes an increase of $40 million within CDC to support HIV prevention efforts consistent with the National HIV/AIDS Strategy. This increased funding would support implementation, data collection, and guideline development for national organizations and State and local education and health agencies to implement science-based interventions in schools settings to prevent HIV, STDs, and teen pregnancy. Funds would also be used to support health departments in their HIV prevention efforts, increase testing and decrease the risk behaviors among groups at highest risk for HIV acquisition, and improve HIV/AIDS program collaboration and service integration with prevention programs for viral hepatitis, STDs, and tuberculosis.

HIV Prevention
There are 1.2 million people living with HIV in the U.S. and 50,000 new infections every year. HIV disproportionately affects African Americans, Latinos and gay men, but unfortunately it seems to be getting less popular attention than it used to.

Question:
1. **What will be done in FY13 to address the epidemic of new infections?**

Answer: Despite increases in the total number of people in the United States living with HIV infection in recent years due to better testing and treatment options, the annual number of new HIV infections has remained relatively stable. However, new infections continue at far too high of a level, with approximately 50,000 Americans becoming infected with HIV each year. Young, black men who have sex with men were the only risk group in the United States to experience statistically significant increases in new HIV infections from 2006–2009. Additionally, Blacks continue to experience the most severe burden of HIV compared to other races and ethnicities, and Hispanics/Latinos are also disproportionately affected by HIV. CDC is committed to achieving the ambitious goals of the National HIV/AIDS Strategy (NHAS) to reduce the number of new HIV infections and reduce HIV-related health disparities. Three action steps are identified: 1) intensify HIV prevention efforts in communities where HIV is most heavily concentrated; 2) expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches; and 3) educate all Americans about the threat of HIV and how to prevent it.

CDC would use the increased funding requested for FY 2013 to address priorities in NHAS. Specifically, CDC would increase HIV Adolescent and School Health funding over the FY 2012 level for cooperative agreements to states, cities, territories, and tribes. This would enable HIV priority areas to develop and implement health policies, programs, and practices, as well as improve HIV and sex education efforts across the country. CDC would also restore funding to several national non-governmental organizations that provided professional development and technical assistance to state and local education agencies, health agency partners, and other organizations working in school health.

Of the increase proposed for HIV Prevention by Health Departments and National Programs to Identify and Reach Highest-Risk Populations, CDC would award $22 million directly to state and local health departments. The increased funds are expected to improve the capacity of jurisdictions to conduct core HIV surveillance activities, and improve the use of surveillance and other programmatic data to improve HIV testing, retention, and re-engagement in medical care activities. Through its recent funding opportunity announcements, CDC emphasized the importance of aligning resources to better match the geographic burden of the HIV epidemic throughout the United States. This resulted in an equitable approach to CDC's HIV funding; additional funding for CDC would reflect a continuation of this approach.

2. What specific prevention efforts are planned to target minority communities?

Answer: During FY 2013, the National HIV/AIDS Strategy's goal of reducing new HIV infections will remain an HHS priority with a particular focus on increasing early diagnosis of HIV infection and active linkage to care. The Secretary's Minority AIDS Initiative Fund (SMAIF) will continue to support the efforts of HHS agencies and offices to increase HIV screening in both medical care and community settings with active linkage to care in community health centers, substance abuse facilities, Title X family planning clinics, college campuses, and many other traditional and non-traditional venues. The awareness of the disproportionate impact that this epidemic has on Black and Latino gay and bisexual men and African American women and Latinas will continue to shape the targeting of education and awareness campaigns in those communities, as well as concurrent HIV testing initiatives. Those populations and jurisdictions that continue to bear the brunt of this epidemic must continue to receive the lion's share of prevention dollars. However, HHS will also continue to support national HIV education and prevention efforts in moderate and low-prevalence jurisdictions and among American Indians, Alaska Natives, Native Hawaiian, Asian American, and Pacific Islanders.

HHS will initiate a demonstration program through the SMAIF to address the HIV/AIDS related disparities seen in racial/ethnic minorities living in the southern United States. This project will be a collaborative effort in which the Centers for Disease Control and Prevention and several other HHS agencies and offices will work in partnership with southern state health departments and community and faith-based organizations to address various structural factors that challenge our prevention and linkage to care efforts among disproportionately impacted racial and ethnic minority communities.

Dystonia

The Dystonia Coalition, part of the Rare Disease Clinical Research Network at the National Institutes of Health (NIH), is making significant progress in recruiting patients into its registry and supporting promising clinical research.

Question:

1. **How can the Department of Health and Human Services, NIH, dystonia researchers and the dystonia patient community continue to make progress on this important initiative?**

Answer: The National Institute of Neurological Disorders and Stroke (NINDS) and the NIH Office of Rare Diseases Research (ORDR) work closely with the Dystonia Coalition, which is part of the ORDR Rare Diseases Clinical Research Network. The Coalition is an international collaboration of medical researchers and patient advocacy groups supported by the NIH. The Coalition is advancing the pace of clinical and translational research in the dystonias to find better treatments and a cure. Because of the extraordinary enthusiasm and collaboration among the scientific and lay dystonia community, the Coalition has expanded to include 44 clinical sites and 13 patient advocacy groups, with several pharmaceutical companies also engaged through participation at the Coalition's annual meeting. Information about the Coalition's activities is widely disseminated through scientific meetings and other outreach efforts, including a website (http://rarediseasesnetwork.epi.usf.edu/dystonia/). The Coalition has overcome the organizational challenges inherent in such a large and broad cooperative effort, fulfilled the regulatory requirements for the initial clinical studies, ensured consistency and sharing of data across clinical sites, and begun clinical studies with dystonia subjects. Initial clinical studies are focusing on natural history of dystonias, collection of biorepository specimens for the use of dystonia researchers via the NINDS Human Genetics Repository, and development of rating scales that can be used to diagnose different forms of dystonia and evaluate their severity over time. The Coalition is also taking steps to encourage junior investigators and senior investigators not previously studying dystonia to move into research on this disease. NIH continues to fund other investigator initiated grants on dystonia—in fact, one of the aims of the Coalition is to fund promising early clinical studies rapidly, and one investigator has already successfully competed for an R01 grant using preliminary data based on a Coalition funded pilot study. This May, the Dystonia Medical Research Foundation, the NIH, and others in the Coalition will hold a scientific workshop on the design of clinical trials for dystonia, which is a key issue in developing new treatments. NIH is encouraged by the progress that the Coalition has made to date, and optimistic that the strong support in the research and patient community, as well as across the NIH, will enable the Coalition to make substantial contributions to improving the outlook for people with dystonia.

Dystonia and Deep-Brain Stimulation

Many patients suffering from generalized dystonia experience significant life improvement after undergoing Deep-Brain Stimulation (DBS). Whereas before their surgery these patients were disabled and immobilized, DBS renders them able to walk and move almost completely normally. However, despite this opportunity for transformational health improvement, some 3rd party payers refuse to reimburse DBS for dystonia patients

because it is considered a Humanitarian Use Device (HUD) and received a Humanitarian Device Exemption (HDE) instead of a full FDA approval. Reimbursement refusal from 3rd party payers essentially blocks dystonia patients from utilizing DBS, even after they've been cleared for the treatment after extensive and exhaustive screening by their physicians.

Do you feel that those dystonia patients that could greatly benefit from DBS should have access to the treatment?

Answer: Currently, only one device has received FDA approval for this indication. Specifically, the Medtronic Activa® Dystonia Therapy system received a Humanitarian Use Device (HUD) Designation on November 27, 2001 and marketing authorization via a humanitarian device exemption (HDE) on April 15, 2003. To date, this device has not been subject to FDA's premarket approval (PMA) process.

An HDE, unlike a premarket approval (PMA) application, is exempt from the effectiveness requirements of the Federal Food, Drug, and Cosmetic Act (the Act). Therefore, an HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. FDA approval of an HDE authorizes an applicant to market a HUD, subject to certain profit and use restrictions set forth in section 520(m) of the Act and Title 21 of the *Code of Federal Regulations* (CFR), Part 814 Subpart H.

The Medtronic Activa® Dystonia Therapy system received HDE approval for unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above.

The FDA's review of the Medtronic Activa Dystonia Therapy HDE concluded that the system was reasonably safe and met the regulatory requirement that the probable benefit from use of the device (in aiding the management of chronic, intractable primary dystonia in patients seven years of age or above) outweighs the risk, taking into account the factors mentioned. The FDA is not involved in decisions regarding health care coverage and reimbursement for medical devices, but does support the use of the Medtronic Activa Dystonia Therapy system for this small, desperate patient population within the approved indications for use.

317 Immunization Program

In 2012, $190 million from the Prevention and Public Health Fund will be transferred to the 317 immunization program.

Question:

1. **How will these funds be used and will those activities continue in 2013 at the same level of support?**

Answer: In FY 2012, the Prevention and Public Health Fund will meet the needs of the Section 317 Immunization Program, as well as provide one-time resources for infrastructure enhancements in health IT, planning and implementation of public health billing systems, adult vaccination, and capacity for vaccinating school-age children. The FY 2013 Budget directs $25 million towards continued progress in the billables project, but eliminates these other one-time enhancements.

Antibiotic Resistance

More than 70 percent of the pathogens that cause healthcare associated infections (HAIs) are resistant to at least one of the antibiotics typically used to treat them. Increasing antibiotic resistance is a serious public health threat. The Centers for Disease Control and Prevention (CDC) play a critical role with regard to surveillance of emerging resistant pathogens, collecting data on antibiotic use and resistance trends, and promoting the appropriate use of antibiotics to help slow the development of resistance.

What are some proposals in the Administrations FY13 budget request that would address the serious need for new antibiotics to treat multi-drug resistant infections?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health, supports basic research to identify new antibiotic targets, translational research to develop new medical countermeasures (drugs, diagnostics and vaccines) and clinical research to study strategies to combat antibiotic-resistant infections. As part of this effort, NIAID provides a broad array of preclinical and clinical research resources to researchers in academia and industry to help facilitate product development. By providing these critical services to the research community, NIAID can help to bridge gaps in the product development pipeline and lower the financial risks incurred by industry to develop novel antibiotics. NIAID plans to continue this important work in Fiscal Year (FY) 2013.

A significant amount of NIAID's drug development portfolio, including research and development of novel antibiotics, is supported by grants awarded through the Institute's Partnerships Program. NIAID's Partnerships Program supports collaborative efforts and multidisciplinary approaches to advance candidate products or platform technologies through the product development pathway, and has supported numerous grants addressing antibiotic resistance since its inception in 2000. Recent awards include work to advance the development of diagnostics and therapeutics for drug-resistant pathogens and pathogens that are at risk for developing drug resistance. In FY 2011, NIAID issued the "Targeting Resistance in Select Gram-Negative Pathogens" phased innovation award research initiative. This initiative targets early-stage research towards the development of novel therapeutic approaches to treat resistant Gram-negative bacteria. NIAID anticipates making awards for this initiative in the spring of 2012. In FY 2012, NIAID issued the "Partnerships for Development of Therapeutics and Diagnostics for Biodefense" which focuses, in part, on the development of new therapeutics

targeting antibiotic-resistant pathogens. Partnership awards are anticipated to be made in FY 2013.

NIAID also supports the preclinical development of new antibacterial agents through contracts to companies involved in novel drug design and synthesis. These contracts were solicited through a Broad Agency Announcement entitled "Development of Therapeutics for Biodefense." Work under these contracts aims to develop four different classes of drugs that have the potential to treat multi-drug resistant (MDR) bacterial infections. A similar Broad Agency Announcement is planned for FY 2013.

To foster clinical research on antibiotic resistance, in January 2012, NIAID released a Request for Applications to support a new leadership group for an antibacterial resistance clinical trial network similar to the existing NIAID HIV/AIDS clinical research networks. The award will be made in FY 2014. The antibacterial resistance leadership group will develop and implement a comprehensive clinical research agenda to address the pressing problem of antibacterial resistance, and will have the capability to test new antibiotics as well as currently available antibiotics in clinical studies; the latter studies will help inform the rational use of existing antibiotic drugs to help limit the development of antibiotic resistance. This work will complement current NIAID-supported clinical trials designed to determine proper antibiotic dose, treatment duration, and whether antibiotic treatment is necessary in all cases.

Questions:

1. **Given that a report card issued last October by the WMD Center gave the U.S. a grade of "F" for our ability to respond to a bioterror attack involving drug-resistant pathogens, does the proposed increase for the Biomedical Advanced Research and Development Authority (BARDA) fund additional antibiotic R&D?**

Answer: BARDA's Broad Spectrum Antimicrobial Program is focused on developing novel antibacterial and antiviral drugs for the treatment or prevention of disease caused by currently defined and future biological threats. Recognizing the immediate value of new antimicrobials in addressing the increasingly prevalent public health threat of antibiotic resistance, as well as the likelihood that antimicrobial resistance will complicate primary treatment of a wide array of threats, BARDA is supporting the development of public-private partnerships for the development of novel antimicrobials. Through these partnerships, BARDAintends to support the development of candidate antimicrobials for their commercial, clinically prevalent infectious disease indications, as long as our private sector partners concomitantly support the development of these products for biodefense threat agent indications. By adopting this approach, BARDA will support the development of new classes of antimicrobials, increase the number of antimicrobial drugs in the developmental pipeline, address the important and immediate threat of antimicrobial resistance, and prepare the nation for the predictable threat of biological terrorism and the unpredictable threat of emerging infectious diseases.

Office of Refugee Resettlement

A number of federally funded programs administered by local refugee resettlement agencies assist refugees in securing employment and housing. These programs have been highly effective at helping refugees achieve self-sufficiency through employment. However,

refugees are only eligible for most benefits and services during their first eight months in the United States. In the current economic climate, it can take refugees longer than eight months to secure sustainable employment which will enable them to afford basic housing for themselves and their families.

Question:

1. **How much does ORR plan to spend in FY '13 for emergency housing assistance to refugees?**

Answer: The FY 2013 President's Budget request is intended to address many refugee needs, including the provision of up to eight months cash and medical assistance for newly arriving refugees. With respect to emergency housing, refugees can access a variety of homelessness prevention and assistance programs through the U.S. Department of Housing and Urban Development or state or county housing programs. HHS Refugee Resettlement funds have not been targeted to emergency housing, beyond the provision of cash assistance and some limited use of refugee social services funds. The FY 2011 and FY 2012 budget requests for refugee social services included an increase of $25 million for emergency services, including housing, but increases were not included for that purpose in that program's final enacted funding levels.

2. **Does this budget account for a possible increase in the Iraqi caseload, provided that the security clearance process is expedited?**

Answer: The FY 2013 Refugee Resettlement request includes sufficient funds to serve 72,500 refugees, a 12% increase over the 65,000 refugees the State Department currently estimates will enter the U.S. in FY 2012. The request is based on the total number of refugees and not on assumptions about which country these additional refugees will arrive from.

Questions for the Record
From Rep. Barbara Lee

Question for the Record: HIV/AIDS & Affordable Care Act
As you may remember, many of my colleagues and I have written to ask you to keep in mind the needs of people with HIV infection and viral hepatitis as it relates to the Essential Health Benefits development under the Affordable Care Act. As you work to finalize the benefits package for states, and continue to implement the Affordable Care Act through 2014 and beyond, can you elaborate on how the Department will ensure individuals at risk have access to tests and evidence-based screening services recommended by the CDC, as well as access to certain classes of drugs, such as HIV and viral hepatitis medications.

Answer: The Essential Health Benefits Bulletin, released on December 16, 2011 detailed the regulatory approach that HHS intends to take to define Essential Health Benefits under Section 1302(b) of the Affordable Care Act. In that bulletin HHS outlined an approach in which states would select from one of four benchmark plan types in defining the Essential Health Benefits for 2014 and 2015. Prescription drugs are one of the ten categories of items and services that are required to be included in every plan subject to the Essential health Benefits. CMS welcome

comments on the approach we intend to propose, as outlined in the bulletin. Further details regarding the essential health benefits will be provided when HHS releases further regulations.

Question for the Record: HIV/AIDS & National AIDS Strategy
Madam Secretary, as you know, there are 1.2 million people living with HIV in the U.S. and 50,000 new infections every year. HIV is disproportionately affecting African Americans, Latinos and gay men. This is an epidemic that is happening in our own neighborhoods and it doesn't seem that people are paying attention to AIDS like they used to. What is the President proposing to do to decrease the number of new infections here at home?

Answer: Although the US HIV epidemic continues to expand on a yearly basis, it does so at a much slower rate than it used to, in part, due to the investments HHS has made over the years in HIV prevention, treatment, and care. Additionally, the percentage of Americans who are personally concerned about becoming infected has increased for the first time in recent years, according to a 2011 Kaiser Family Foundation Poll.

The President's National HIV/AIDS Strategy (NHAS), released in 2010, specifically addresses the need to decrease new HIV infections in the US. In addition to improving access to quality care and reducing HIV-associated health disparities, the NHAS calls for a coordinated national response that intensifies HIV prevention efforts in communities where HIV is most heavily concentrated; expands targeted efforts to prevention HIV infection using evidence-based, high-impact, combination prevention approaches; and educates all Americans about the threat of HIV and how to prevent it. In response to the NHAS, HHS has implemented expanded HIV testing initiatives for males who have sex with other males (MSM) and other groups at increased risk. HHS is testing new combinations of prevention packages to identify which components are most effective in reducing new HIV infections and has launched a new HIV prevention campaign -- Act against AIDS -- to raise awareness among all Americans and to reduce risk of infection among gay and bisexual men, African Americans, Latinos, and other communities heavily affected by HIV.

Question for the Record: Disability Programs:
The President's FY 2013 budget proposes again to consolidate the 11 disability programs at the National Center on Birth Defects and Developmental Disabilities within the Centers for Disease Control and Prevention into one line. As you know, many in Congress expressed our concerns over this exact proposal in the President's FY 2012 budget. There was so much concern over the President's proposal that Congress included report language that accompanied the Military Construction and Veterans Affairs and Related Agencies Appropriations Act of 2012 that rejected the proposed consolidation. Furthermore, the conferees directed that any new consolidation put forward by the administration be accompanied by an "assessment of the needs of people with disabilities that includes the categories of disabilities currently served, validates the value of such a consolidation, considers the input of stakeholders, and establishes the basis for any proposed efficiencies and commonalities. What is the Administration's plan to fulfill the requirements laid out in the conference committee report?

Answer: CDC was not able to address the Congressional request for a needs assessment in advance of the FY 2013 Budget. CDC has been and continues to conduct a needs assessment of all programs.. For example, the National Center for Birth Defects and Developmental Disabilities (NCBDDD) conducted a series of partner meetings in late February and early March regarding the FY 2013 Budget. These meetings included a broad NCBDDD Advocacy Coalition meeting as well as a dedicated meeting for disability and health partners.

This most recent work follows the extensive efforts undertaken in support of the consolidations proposed in the FY 2012 Budget. CDC initiated a planning effort designed to develop and implement a 3-year transition plan to facilitate adoption of the proposed consolidation. From February to August 2011, CDC conducted a series of partner engagement meetings designed to afford CDC partners and grantees the opportunity to contribute in the development of the transition plan.

CDC's goal was to develop a plan that: engaged partners in managing the anticipated transition process; fulfilled existing funding obligations; adhered to existing legislative mandates; informed this transition process through CDC's strategic planning, priority setting, and pilot testing efforts; and developed revised performance measures that reflected the proposal. The proposed plan included an effort to implement a modular FOA process to funding opportunities for a variety of disease- specific programs that are engaged in similar activities (epidemiology/surveillance, research, education; and public health practice).

CDC is currently collaborating with the Association of University Centers on Disability to conduct the needs assessment requested by Congress.

Question: For more than 30 years state and local health departments have relied up the flexibility of the Preventive Health and Health Services Block Grant to address their unique local solutions for a wide variety problems and needs. We are seeing state support for hospital and emergency preparedness being cut in this budget, and also the complete elimination of the CDC Prevention Block Grant. What impact will these proposed cuts have on the basic public health protection of our nation?

Answer: Through CDC's existing and expanding activities, there is substantial funding to state health departments to address community health needs. The activities currently supported by the Preventive Health and Health Services Block Grant may be more effectively and efficiently implemented through the new Coordinated Chronic Disease Prevention and Health Promotion Grant. The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and

other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. This funding has supported grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

Question for the Record: Chronic Disease Coordination

Less than 4 cents of every health care dollar is spent on prevention, yet chronic diseases account for 70% of deaths and a huge healthcare cost burden. The CDC budget proposes the consolidation of several existing categorical programs into a single coordinated program. Can you explain what efficiencies you hope to gain from this proposal and what assurances you can give to those who are concerned about losing the identity of disease specific funding streams?

Answer: The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. The proposed FY 2013 CCDPHPP will increase the average awards to states from approximately $2.6 million to approximately $4.5 million. This increase in funding will permit states, tribes, and territories to support a broader range of programs targeting the leading causes of chronic disease-related death and disability and their associated risk factors. Within the total program level, no more than 20 percent of total funding will be allocated to program administrative costs, including CDC's technical assistance, evaluation, oversight, and management activities. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services.

The efficiencies achieved from a consolidated approach to chronic-disease prevention programming will:

- Allow all states to receive funding to support core chronic disease prevention and health promotion functions while increasing the opportunity to invest a greater share in program activities;
- Provide states with the flexibility to focus a greater share of program implementation funding on addressing the aggregate chronic disease burden in their respective state;

- Offer states greater flexibility to organize health departments and programs without the fiscal and programmatic limitations currently placed on the individual funding streams;
- Allow states to focus on health outcomes and public health impact rather than tracking multiple funding sources for each chronic disease separately; and
- Consolidate funding, providing CDC with the opportunity to expand its reach to address chronic diseases with the full complement of targeted programs.

At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

Question for the Record: Prevention and Public Health Fund

The same the President's budget was submitted to Congress, the payroll tax bill passed to cap the fund at $1 billion for the next several years. Can you explain the important role that this Fund plays to improve public health and how the Administration intends to close the $250 million hole in your budget request that is caused by the elimination of the FY 2013 increase to the Fund?

Answer: The Middle Class Tax Relief and Job Creation Act of 2012 Uses a portion of funding available under the Prevention and Public Health Fund as an offset to pay for extending the current payroll tax rate, Medicare physician reimbursement rates, and unemployment assistance. The Act reduces the overall amount available from the Prevention and Public Health Fund by $6.25 billion in budget authority and anCBO has estimated $5 billion in outlay savings over ten years, leaving $1 billion available in FY 2013 As we did for FY 2010, 2011, and 2012, we intend to work with Congress as we formulate plans to allocate the $1 billion for 2013.

Question for the Record: Hepatitis

Many of us on the subcommittee were gratified to note the release of the HHS-Wide Action Plan for the Prevention, Care and Treatment of Viral Hepatitis (Action Plan). The importance of implementing the plan is becoming increasingly clear, particularly as new studies emerge on the mortality rate due to hepatitis and the cost-effectiveness of testing baby boomers. However, it does not appear that there is funding associated with the Action Plan in the fiscal year 2013 (FY13) budget proposal. I note the additional $10 million in CDC's budget request (a modest amount), but what about tbe rest of the Public Health Service? How will SAMHSA, HRSA, CMS, the Office of Minority Health and other agencies respond to the activities articulated in the plan?

Answer: The Office of HIV/AIDS and Infectious Disease Policy has convened a Viral Hepatitis Implementation Group composed of representatives from CDC, SAMHSA, HRSA, CMS, FDA, NIH, AHRQ, Office of Minority Health, Office on Women's Health, National Vaccine, Program Office, Bureau of Prisons and the Department of Veterans Affairs. The Implementation Group meets regularly and is currently drafting a year-one report on each agency's response to the activities articulated in the Action Plan. Many agencies are leveraging existing resources to address activities outlined in the Action Plan. The year-one report is expected to be available in the summer of 2012.

Question for the Record: Community Transformation Grants

I was pleased to see new Community Transformation Grants to 61 states and localities in 2011. What measures and standards are HHS and CDC using to ensure that we receive a valuable return on this investment? What specific health outcome improvement goals have been set?

Answer: The Community Transformation Grants (CTG) program builds upon CDC's past successes and lessons-learned to improve community health and marks the next stage of CDC's commitment to community-based programs. The CTG program supports states and communities to develop and implement initiatives that prevent chronic diseases, the leading causes of death and disability. CTGs focus on five strategic priority areas: 1) tobacco-free living, 2) active living and healthy eating, 3) increased use of high-impact clinical preventive services to prevent and control high blood pressure and high cholesterol, 4) social and emotional wellness, and 5) healthy and safe physical environments.

CTG awards were announced in September 2011. Sixty-one states and communities received awards. Thirty-five states and communities will implement evidence- and practice based programs designed to improve health and wellness. Twenty-six states and communities will work to build capacity to implement changes by laying a solid foundation for community prevention efforts to ensure long term success. Seven national networks of community based organizations were also funded. The four dissemination awardees will work to disseminate CTG strategies within their national network of local affiliates. The three acceleration awardees will support local communities in assessing and addressing CTG health priorities. Through this effort, more than 1 in 3 U.S. citizens are being reached, including more than 20 million Americans in rural and frontier areas.

By 2016, CTG states and communities will promote healthy lifestyles by:

- Increasing access to smoke-free or tobacco-free environments in settings such as workplaces, restaurants, and bars; multi-unit housing; schools; campuses; and outdoor places.
- Increasing access to healthy food and beverage options in schools, afterschool programs, early child care settings, workplaces, and other community settings.
- Increasing access to physical activity opportunities in schools, afterschool programs, early child care settings, workplaces, and other community settings.
- Increasing access to systems and opportunities that support control of high blood pressure and high cholesterol in health care and other community settings.

CTG grantees must align their efforts with the following program objectives:

- Reduce death and disability due to tobacco use by 5 percent in the implementation area.
- Reduce the rate of obesity through nutrition and physical activity interventions by 5 percent in the implementation area.
- Reduce death and disability due to heart disease and stroke by 5 percent in the implementation area.

The CTG program has a robust evaluation plan that includes four components:

1) Performance Monitoring to track progress on objectives and milestones, as well as the potential and actual reach of CTG strategies.
2) Population-Level Surveillance to measure changes in attitudes, risk behaviors, and other behavioral risk factors and indicators for a range of age and target population groups in select communities.
3) Cost Studies to collect and analyze cost data for funded communities aligned with the CTG Strategic Directions.
4) Enhanced Evaluation Studies to assess the actual and projected impact of specific CTG strategies on health outcomes.

Questions for the Record
From Rep. Jesse L. Jackson

Access to Family Planning Services
Research shows that even small cost-sharing requirements can put contraception out of reach for many women and families. These monthly charges quickly accumulate for women who rely on this method of preventive care, just one reason why the new policy announced by the Administration to ensure contraceptive coverage for millions of women is so important.

Because increased access to birth control has been shown to decrease the number of unplanned pregnancies, do you expect to see a downward trend in the number of women seeking abortion services as a direct result of this new policy?

Answer: The scientists and experts at the Institute of Medicine whose recommendations were adopted by HHS, relied on scientific evidence that there are tremendous health benefits that come from using contraception, which can allow women to plan pregnancies and help ensure they and their children stay healthy. Scientists have abundant evidence that birth control has significant health benefits for women and their families and is documented to significantly reduce health costs.

A recent brief issued by the HHS Assistant Secretary for Planning and Evaluation entitled, "The Cost of Covering Contraceptives through Health Insurance," found that "each year, public funding for family planning prevents about 1.94 million unintended pregnancies, including almost 400,000 teen pregnancies." This brief can be accessed here: http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml

Lead Poisoning and the Healthy Homes Program
Since the program's creation, the CDC has prevented approximately 100,000 children from being poisoned by lead each year through the Healthy Homes and Lead Poisoning Prevention Program. According to 2009 Chicago data, of the over 85,000 children tested: 3,143 had a blood lead level of between 6 and 9 and 1,258 had a BLL of above 10.

As the Administration again proposes to consolidate the Healthy Homes and Lead Poisoning Prevention Program, how will you ensure that the nation's most vulnerable

children are tested for lead poisoning and ensure that if those children test positive that treatment and environmental remediation services are provided?

Answer: The FY 2013 Budget proposes a new program—Healthy Home and Community Environments—that will incorporate the National Asthma Control Program (NACP) and the Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The FY 2013 request for the Healthy Homes and Community Environments program is $27.3 million.
The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors.

Given the drastic cuts to CDC's Lead Poisoning Prevention Program that could essentially end all state cooperative agreements, what are your proposed strategies moving forward to ensure that the essential services (emergency response to children with lead poisoning, home inspections that include environmental health components, surveillance, etc.) provided by state and local health departments to vulnerable children are not lost?

Answer: With FY 2012 funding, CDC's Healthy Homes and Lead Poisoning Prevention Program will continue to provide lead expertise and analysis at the national level and remain a valuable resource to state and local agencies by providing the following:

- Surveillance Support: Provide software and technical assistance to support the Healthy Homes and Lead Poisoning Surveillance System (HHLPSS), which gathers information related to lead and other health hazards in homes.
- Epidemiological Support: Maintain staff to provide expertise and epidemiological support in response to a lead poisoning outbreak.
- Subject Matter Expert Support: Maintain the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The ACCLPP advises and guides the Secretary and Assistant Secretary of the U.S. Department of Health and Human Services and the Director of the Centers for Disease Control and Prevention regarding new scientific knowledge and technical developments and their practical implications for childhood lead poisoning prevention efforts.

Global Immunization Program
The CDC has been a leader in efforts to provide vaccines and immunizations to children in developing countries for decades. Through the Measles Initiative and the Global Polio Eradication Initiative, the CDC has collaborated with a diverse range of partners including UNICEF, WHO, Rotary International, and the American Red Cross, in their efforts to eliminate measles and eradicate polio.

One such point of collaboration includes providing financial and technical support to program operations through UNICEF and WHO for vaccine procurement. FY 2013, the President requested a total of just over $175 million to fund the CDC's global immunization program, with a request to increase funding allocated to polio eradication efforts.

Can you please speak to how this requested funding will continue to support these partnerships and efforts, and what return on investment can be expected from this request?

Answer: In addition to supporting more frequent and intensive assistance for the remaining polio-endemic and re-infected countries, the Budget's proposed investment in global polio eradication will serve to leverage funding by other global donors for the Global Polio Eradication Initiative, just as the activation of the CDC Emergency Operations Center catalyzed other partners to take action to treat polio, as noted in a resolution approved by the January 2012 World Health Organization's Executive Board. CDC will continue to leverage partnerships with WHO, UNICEF, Rotary International, and the Bill and Melinda Gates Foundation as means to achieve the eradication of polio and to realize even greater improvements in global health. For example, bolstering routine immunization and increasing the use of new vaccines to protect against pneumonia, diarrhea, and meningitis could prevent an additional 2 million child deaths annually.

CDC has long been engaged in efforts and partnerships to support vaccination of children in developing countries. Since 1991, critical funding has been provided to CDC for global vaccination programs, including specific appropriations for polio eradication, measles mortality reduction, and strengthening routine immunizations. The efforts of CDC, other U.S. agencies, national governments, and multiple partners have led to major progress in addressing global immunization goals and reducing deaths due to vaccine-preventable diseases. Polio cases have dropped by 99% since 1988, measles deaths declined by 78% from 2000 through 2008, and more than 2.5 million vaccine preventable disease (VPD) deaths are stopped each year through routine immunization. CDC has made significant progress in reducing or eliminating most vaccine-preventable diseases in the United States, but our efforts to prevent them in other parts of the world are critical to protecting Americans from reintroduction of these diseases.

In addition to supporting implementation of vaccination activities and laboratory confirmation of measles cases, CDC is a lead technical and financing partner of the Global Polio Eradication Initiative (GPEI) which began in 1988, when the World Health Assembly announced a goal to eradicate polio and established the GPEI to stop the spread of the virus that causes polio. GPEI is led by national governments with support from the four spearheading partners (the World Health Organization, United Nations Children's Fund, Rotary International, and CDC) and the Bill and Melinda Gates Foundation. The U.S. is committed to global polio eradication and invested over $35 billion between 1955 and 2005 and will continue to invest billions into the future to pay for polio vaccination. These historical and future investments translate into over 1.7 billion vaccinations that prevent approximately 1.1 million cases of paralytic polio and over 160,000 deaths, thus saving Americans hundreds of billions of dollars in treatment costs. Due to treatment

cost savings, the investment implies net benefits of approximately $180 billion, even without incorporating the intangible costs of suffering and death and of averted fear.[7]

Chronic Disease and Prevention Coordination
Less than 4 cents of every health care dollar is spent on prevention, yet chronic diseases account for 70% of deaths and a significant cost burden of our healthcare system. Again, the CDC budget proposes the consolidation of several existing categorical programs into a single coordinated program.

Can you explain what efficiencies you hope to gain from this proposal and what assurances you can give to those who are concerned about losing the identity of disease specific funding streams, particularly chronic diseases that aren't as widely known or focused on?

Answer: The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. The proposed FY 2013 CCDPHPP will increase the average awards to states from approximately $2.6 million to approximately $4.5 million. This increase in funding will permit states, tribes, and territories to support a broader range of programs targeting the leading causes of chronic disease-related death and disability and their associated risk factors. Within the total program level, no more than 20 percent of total funding will be allocated to program administrative costs, including CDC's technical assistance, evaluation, oversight, and management activities. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

Focal segmental glomerulosclerosis
Focal segmental glomerulosclerosis (FSGS) is five times more prevalent in the African American community than the general population. This constitutes a serious health disparity and merits additional research.

What is NIH planning to do in the future to be more proactive in supporting research on the disparate effect of FSGS and nephrotic syndrome on minority populations as well as the best treatment options for these groups?

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[7] Retrospective Cost-Effectiveness Analyses for Polio Vaccination in the United States by Kimberly M. Thompson and Radboud J. Duintjer Tebbens, *Risk Analysis* 2006;26(6):1423-1440.

Answer: Focal segmental glomerulosclerosis (FSGS) is a type of glomerulonephritis that often progresses to kidney failure. The NIH is deeply concerned about people with glomerular diseases such as FSGS, and promotes and supports studies of glomerular diseases in a number of ways. These include funding of research projects; direct solicitation of research in a particular area; conducting cutting-edge research through the NIH Intramural Research Program; and support for scientific meetings where state-of-the-art science is discussed.

The NIH supports a robust portfolio of investigator-initiated research projects into all forms of kidney disease. NIH also supports research on glomerular diseases through the Nephrotic Syndrome Rare Diseases Clinical Research Network (NEPTUNE), a multi-site, multidisciplinary collaborative research and education network.

The NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Program Announcement PA-10-113, "Grants for Research in Glomerular Diseases," is encouraging studies to enhance our understanding of the progression of the various primary or secondary forms of glomerular disease, including FSGS. To date, the NIDDK has funded five projects under this Announcement, which will remain open until May 2013. One of the projects is examining how a defective protein caused by a gene mutation results in kidney disease, while another is studying why FSGS reoccurs after transplantation of a new, healthy kidney, and how the drug rituximab may protect kidney function of the transplanted organ.

Recent studies have shown that African Americans with two variant copies of the APOL1 gene have about a 4% lifetime risk of developing FSGS. These findings explain nearly all of the excess risk of non-diabetic kidney failure in African Americans, and will have important implications for understanding the differences in kidney disease risk across populations. NIDDK intramural scientists played a prominent role in these investigations.

Looking forward, the NIH is convening a scientific conference titled "Glomerular Disease Pathophysiology, Biomarkers, and Registries for Facilitating Translational Research" in April 2012. This meeting will explore practical next steps that might be taken by the scientific investigators, the pharmaceutical industry, professional societies, and disease advocacy groups in FSGS and other forms of nephrotic syndrome.

Through efforts such as these, we continue to make strides in understanding these disorders, knowledge we are hopeful will ultimately lead to effective prevention, treatment, and curative approaches. NIH is committed to pursuing new and emerging scientific opportunities in FSGS and nephrotic syndrome research.

Dystonia Coalition

It has come to my attention that the *Dystonia Coalition*, part of the Rare Disease Clinical Research Network at the National Institutes of Health (NIH), is making significant progress in recruiting patients into its registry and supporting promising clinical research.

How can the Department of Health and Human Services, NIH, dystonia researchers and the dystonia patient community continue to make progress on this important initiative?

Answer: The National Institute of Neurological Disorders and Stroke (NINDS) and the NIH Office of Rare Diseases Research (ORDR) work closely with the Dystonia Coalition, which is part of the ORDR Rare Diseases Clinical Research Network. The Coalition is an international

collaboration of medical researchers and patient advocacy groups supported by the NIH. The Coalition is advancing the pace of clinical and translational research in the dystonias to find better treatments and a cure. Because of the extraordinary enthusiasm and collaboration among the scientific and lay dystonia community, the Coalition has expanded to include 44 clinical sites and 13 patient advocacy groups, with several pharmaceutical companies also engaged through participation at the Coalition's annual meeting. Information about the Coalition's activities is widely disseminated through scientific meetings and other outreach efforts, including a website (http://rarediseasesnetwork.epi.usf.edu/dystonia/). The Coalition has overcome the organizational challenges inherent in such a large and broad cooperative effort, fulfilled the regulatory requirements for the initial clinical studies, ensured consistency and sharing of data across clinical sites, and begun clinical studies with dystonia subjects. Initial clinical studies are focusing on natural history of dystonias, collection of biorepository specimens for the use of dystonia researchers via the NINDS Human Genetics Repository, and development of rating scales that can be used to diagnose different forms of dystonia and evaluate their severity over time. The Coalition is also taking steps to encourage junior investigators and senior investigators not previously studying dystonia to move into research on this disease. NIH continues to fund other investigator initiated grants on dystonia—in fact, one of the aims of the Coalition is to fund promising early clinical studies rapidly, and one investigator has already successfully competed for an R01 grant using preliminary data based on a Coalition funded pilot study. This May, the Dystonia Medical Research Foundation, the NIH, and others in the Coalition will hold a scientific workshop on the design of clinical trials for dystonia, which is a key issue in developing new treatments. NIH is encouraged by the progress that the Coalition has made to date, and optimistic that the strong support in the research and patient community, as well as across the NIH, will enable the Coalition to make substantial contributions to improving the outlook for people with dystonia.

Emerging Infectious Disease

Infectious disease epidemics have received high-level political attention in recent years. A report released by the National Intelligence Council addresses the national security implications of specific diseases and global health. Additionally, the Bush administration's National Security Strategy gave attention to the threats of emerging infectious diseases, and funding commitments to protect the health of Americans followed.

Diseases know no borders, meaning that security and global health efforts are often carried out hand-in-hand. Two examples include collaboration between DoD, CDC and WHO in monitoring disease outbreaks globally, and UNICEF's negotiation of "Days of Tranquility" in conflict zones to allow for children to be vaccinated.

How do efforts led by the CDC to provide vaccinations to children in developing countries, help protect the health and security of Americans?

Answer: Despite the extraordinary progress in reducing deaths and disease through more widespread vaccination programs, many children still do not fully benefit from all available vaccines. WHO estimates that approximately 8.8 million children under 5 years of age die each year around the world, mostly in poor countries of Asia and Africa. More than 2 million of these deaths, or over 20%, could be prevented by widespread use of vaccines that are currently

available in developed countries. Widespread introduction of these new and underused vaccines to all countries depends on overcoming key challenges: having an adequate vaccine supply, improving immunization system capacity, sustaining partnerships for synergy in reaching targets and having adequate financial support. In addition, as a well-accepted and demanded community health program, the immunization service delivery platform is key in ensuring equitable distribution of other essential health services and decreasing morbidity and mortality from other diseases.

In an era of mass travel and global epidemics, the health of U.S. citizens is closely related to disease occurrence in other countries. Thus, support for immunization programs worldwide contributes toward providing an "umbrella of protection" for the United States, as well as fulfilling the U.S. government's broader commitment to global health. CDC's global health mission is "to protect and improve health globally through science, policy, partnership and evidence-based public health action." CDC leads and contributes to public health activities globally by providing technical leadership and serving as a global reference laboratory. CDC's global health activities complement the United States' foreign aid activities to support security, development, trade, human rights, and ethics.

Our global immunization activities improve national security by supporting international development efforts and improving regard of the United States around the world. Through innovative collaborations among public health, defense, and NGOs, we have made progress in protecting children in some of the most dangerous parts of the world. Such collaborations are challenging and complex, but they are important to achieving our global immunization goals of protecting the health of Americans and global citizens by preventing disease, disability, and death.

Global Health and Immunization Initiatives
President Obama has stated that global health is a key pillar of US foreign aid and diplomatic efforts. By requesting increases to key global immunization programs and initiatives in the FY 13 budget, including the Global Alliance for Vaccines and Immunization and global polio eradication efforts through the Centers for Disease Control and Prevention, the Administration has indicated expanding access to vaccines and immunizations for children in developing countries is a priority.

Why do global childhood immunizations play such a vital role in the context of broader foreign aid efforts, and why should the US government and the CDC continue to be a leader in these efforts?

Answer: Despite the extraordinary progress in reducing deaths and disease through more widespread vaccination programs, many children still do not fully benefit from all available vaccines. WHO estimates that approximately 8.8 million children under 5 years of age die each year around the world, mostly in poor countries of Asia and Africa. More than 2 million of these deaths, or over 20%, could be prevented by widespread use of vaccines that are currently available in developed countries. Widespread introduction of these new and underused vaccines to all countries depends on overcoming key challenges: having an adequate vaccine supply, improving immunization system capacity, sustaining partnerships for synergy in reaching targets

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Spiritual Care and the Affordable Care Act
Madam Secretary, on October 18 of last year I joined 49 other Members of the House of Representatives. The letter asked that you use whatever authority you have under the Affordable Care Act to accommodate the needs of Christian Scientists and other Americans who rely on spiritual care for their health and well-being. Our concern is that these Americans may be mandated to purchase insurance that may not cover the care upon which they rely.

While we have not received a response from HHS, would you please inform the Committee as to what steps you are taking or considering to address the concerns of certain spiritual groups with regards to the implementation of the Affordable Care Act?

Answer: We recently published a bulletin in December in which we described our intended regulatory approach for defining the essential health benefits (EHB) package that health insurance coverage offered in the individual and small group markets, including on Exchanges, must offer. That bulletin describes an approach under which each state would pick an existing health plan as a benchmark for covered services required as part of the EHB package. If a state picks as its benchmark a plan that offers coverage for religious non-medical health care, plans required to offer EHB must also offer those services. In addition, the Affordable Care Act does not preclude issuers from offering additional benefits above those minimally required, including benefits for Americans who rely on spiritual care for their health care needs.

We carefully considered stakeholder input in developign our intended approach to defining essential health benefits that is reflected in the Bulletin, and we look forward to continuing to work with stakeholder groups to discuss their particular needs and explore this further. It is our goal to provide for the health care needs of Americans of all religious and belief systems and we will carefully consider stakeholder comments as we continue to implement the Affordable Care Act.

Viral Hepatitis

Madam Secretary, HHS recently released an Agency-wide Action Plan for the Prevention, Care and Treatment of Viral Hepatitis. The importance of implementing the plan is becoming increasingly clear, particularly as new studies emerge on the mortality rate due to hepatitis and the cost-effectiveness of screening. However, it does not appear that there is funding associated with the Action Plan in the FY 13 proposal.

While a modest $10 million included in CDC's budget request, what about the rest of the Public Health Service? How will SAMHSA, HRSA, CMS, the Office of Minority Health and other agencies respond to the aetivities articulated in the plan without set aside funding?

Answer: Many of the plan's priorities are being carried out by leveraging existing resources within the Department. The Viral Hepatitis Implementation Group composed of representatives from across HHS, the Bureau of Prisons, and the Department of Veteran's Affairs, meets regularly to proactively identify opportunities for inter- and intra-departmental collaborations. The group is currently drafting a year-one report on each agency's response to the activities articulated in the Action Plan. That report is expected to be available in the summer of 2012. Leverage of existing resources has enabled the compilation of a federally-developed educational materials inventory that will be posted on the CDC National Prevention Information Network (NPIN) website and available in support of May Hepatitis Awareness Month.

Preparedness and Response

Since 2001, states have significantly improved and demonstrated their ability to prevent, respond to, recover from, and reduce the effects of a full range of threats and hazards due to federal investments in preparedness and response initiatives. However, no state or community is ever completely prepared to address the health and medical consequences of a major disaster, terrorist event, foodborne illness outbreak, or pandemic. The President's budget proposes to combine, consolidate and reduce funding for preparedness and response activities.

Do you believe that our nation is well enough prepared for a disaster, man-made or natural, that we can now reduce funding for core public health security programs such as Public Health Emergency Preparedness at CDC?

Given the fact that there is no year in the United States absent of a major natural or man-made disaster, how important are the gains made with the federal investments in the Public

Health Preparedness Cooperative Agreements and the Hospital Preparedness Program? Also with hospitals serving as the first and last line of defense in any given community when dealing with extreme casualties from a public health disaster, what is the rationale for cutting the Hospital Preparedness Program by $125 million, or nearly 33 percent in FY 2013?

Answer: Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. Initially, this funding was to support grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

The Administration is committed to cutting the deficit, restoring fiscal sustainability, and achieving better performance with the resources we have. The Budget proposes a 33 percent reduction to HPP. In addition, current efforts to align preparedness grants to improve effectiveness may lead to administrative efficiencies and reduce costs to the programs. In FY 2012, the first joint funding opportunity announcement was issued for the PHEP and HPP programs; the streamlining of these grants will reduce the administrative burden and will accrue savings to the program at both the Federal and grantee levels. By enhancing cohesion between the preparedness programs, states will also be able to make more efficient use of the resources, which is imperative in a constrained budget environment.

Presently, the Department's preparedness and response activity are managed and funded separately but maintain a high degree of coordination between the two, which is vital to an effective response. The Department utilizes a variety of training exercises and working groups to ensure that preparedness planners and those engaged in disaster response share information and best practices to continuously improve our Nation's capabilities in support of all-hazards preparedness. The Department is also engaging across the healthcare spectrum of State and local actors to work with emergency medical response services, public health departments, behavior health experts, and hospitals in supporting healthcare coalitions which are ready for whole community disaster response. Viewing preparedness and response efforts under this paradigm not only enhances our Nation's response capabilities and resiliency, but also supports more effective and efficient exchange of information during a disaster.

Food Safety

The rapid changes in the food supply system and the intricate farm-to-fork supply chain have created significant new responsibilities for food safety protection programs. In addition to a shrinking pool of trained food safety personnel, the economic downturn has forced many state and local agencies to lay off staff, causing additional strain on states' abilities to protect the nation's food supply.

With an estimated one in six Americans sickened by foodborne diseases each year, resulting in an estimated 128,000 hospitalizations and 3,000 deaths at an annual cost of $152 billion, what are the challenges of keeping our food supply safe? What would be the

consequences if we lost federal funding for food safety surveillance and response in such a situation as a food borne disease outbreak?

Answer: Keeping the U.S. food supply safe is a complex challenge. Today's food safety system must meet the demands of a food supply system vastly different from 100 years ago, or even 10 years ago. Our food supply is truly global -- 15 percent of food overall is imported. When you look at specific commodities, the percentages are even greater – approximately 75 percent of seafood is imported; approximately 20 percent of vegetables is imported; and approximately 50 percent of fruit is imported.

Our food supply is more technologically advanced and complex, allowing foods to travel longer distances and be held in ready-to-eat form for longer periods of time. There are new hazards: new pathogens are emerging and old pathogens are turning up in foods in which they had not been previously identified. In addition, as the demographics of our country change, there is a larger percentage (about 30 percent) of people at increased risk for foodborne illness.

It is these challenges and the persistent occurrence of foodborne outbreaks that inspired Congress to enact the FDA Food Safety Modernization Act (FSMA). The preventive controls framework envisioned in FSMA is a significant tool for modernizing our food safety system to meet the challenges of today's food supply.

The consequences of loss of federal funding for food safety surveillance and response would be far reaching. Recent efforts to streamline and enhance surveillance activities on the part of FDA and the Centers for Disease Control and Prevention (CDC) would be greatly curtailed, and our ability to react quickly to a foodborne disease outbreak, such as the Listeria illnesses and deaths linked to whole cantaloupe, would be severely hampered. Tracing an outbreak to its source would be more difficult. Frequently there may be multiple common products identified and multiple points of service involved in an outbreak.

Product traceback activities are very resource-intensive. Currently, FDA and CDC work together to determine the cause of an outbreak, tracing records and sources back through the supply chain and making sure that potentially contaminated product is removed from the marketplace and no longer poses a threat to consumers. Loss of funding could lead to a slower identification of the pathogen causing the illnesses and identification of the contaminated food product. The interaction of FDA, CDC, the US Department of Agriculture, and state and local public health officials, as well as the affected industry, is crucial in this endeavor. The ability to follow up at the source of an outbreak and identify what practices may have led to the contamination is essential to inform future prevention activities and to serve as the basis of outreach to industry in an effort to provide more immediate guidance.

Surveillance activities and trending the data also allow FDA to gauge the effectiveness of current food safety initiatives in order to develop and plan future activities to prevent and/or reduce foodborne illnesses.

Preventive Health and Health Services Block Grant
For more than 30 years, state and local health departments have relied up the flexibility of the Preventive Health and Health Services Block Grant to address their unique local solutions for a wide variety problems and needs. With state support for hospital and emergency preparedness being cut in this budget and the complete elimination of the CDC

Prevention Block Grant what impact will these cuts have on the basic public health protection of our nation?

Answer: Through CDC's existing and expanding activities, there is substantial funding to state health departments to address community health needs. The activities currently supported by the Preventive Health and Health Services Block Grant may be more effectively and efficiently implemented through the new Coordinated Chronic Disease Prevention and Health Promotion Grant. The Budget includes $379 million, an increase of $129 million above FY 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the five year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes. Since 2001, HHS has provided $13 billion to States through the Hospital Preparedness Program (HPP), funded through the Assistant Secretary for Preparedness and Response, and Public Health Emergency Preparedness (PHEP) grants, funded through the Centers for Disease Control and Prevention. This funding has supported grants for planning and exercises and to build States' base capabilities in preparedness and response. States have made significant progress in all-hazards preparedness over the last few years through the use of these resources, which has been evident in States' increasingly ability to provide disaster response without request for Federal resources.

Prevention and Public Health Fund
Ironically, the same week that your budget was submitted to Congress, the payroll tax bill passed to cap the Prevention and Public Health Fund at $1 billion for the next several years.

Can you explain the important role that this Fund plays to improve public health and how the Administration intends to close the $250 million hole in your budget request that is caused by the elimination of the FY 2013 increase to the Fund?

Answer: The Middle Class Tax Relief and Job Creation Act of 2012 USES A PORTION OF funding available under the Prevention and Public Health Fund as an offset to pay for extending the current payroll tax rate, Medicare physician reimbursement rates, and unemployment assistance. The Act reduces the overall amount available from the Prevention and Public Health Fund by $6.25 billion in budget authority and CBO estimated $5 billion in outlays savings over ten years, leaving $1 billion in FY 2013 As we did for FY 2010, 2011, and 2012, we intend to work with Congress as we formulate plans to allocate the $1 billion for 2013.

Environmental Health/Lead
Since the program's creation, the CDC has prevented approximately 100,000 children from being poisoned by lead each year through the Healthy Homes and Lead Poisoning Prevention Program.

As the Administration again proposes to consolidate the Healthy Homes and Lead Poisoning Prevention Program, how will you ensure that the nation's most vulnerable children are tested for lead poisoning and ensure that if those children test positive that treatment and environmental remediation services are provided?

Given the drastic cuts to CDC's Lead Poisoning Prevention Program that could essentially end all state cooperative agreements, what are your proposed strategies moving forward to ensure that the essential services (emergency response to children with lead poisoning, home inspections that include environmental health components, surveillance, etc.) provided by state and local health departments to vulnerable children are not lost?

Answer: The FY 2013 Budget proposes a new program—Healthy Home and Community Environments—that will incorporate the National Asthma Control Program (NACP) and the Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The FY 2013 request for the Healthy Homes and Community Environments program is $27.3 million.

The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors.

Overall Sequestration
With the looming threat of sequestration due to the inability of Joint Select Committee on Deficit Reduction to act, what impact would 8 to 9 percent, line-by-line, reduction have on the HHS budget, and the ability to carry out vital public health services?
The Congressional Budget Office (CBO) has estimated that, , automatic sequestration would result in a 7.8 percent reduction to discretionary nondefense appropriations not exempt from sequestration in 2013. Some HHS activities, such as programs administered by the Indian Health Service and the Health Centers program administered by the Health Resources and Services Administration, are subject to a special rule written into the Budget Control Act that limits the amount that can be reduced by the sequester.

A reduction of this magnitude would have real consequences. For example, HHS estimates that a 7.8 percent reduction could:

- Reduce funding from AIDS Drug Assistance Programs that could resulting in 12,000 fewer patients served.

- Result in 75,000-90,000 children losing Head Start services.
- Eliminate more than 2,000 new and competing research project grants awarded by the NIH.
- Result in the loss of 1,600 FDA inspectors, epidemiologists, safety experts, and scientists that review drug, vaccine and device applications.
- Result in almost 500,000 fewer individuals receiving critical mental health services through the Mental Health Block Grant.

The Administration has been clear that Congress needs to avoid a sequester by passing balanced deficit reduction – at least as much as the Budget Control Act required of the Joint Select Committee on Deficit Reduction to avoid sequestration. The President's Budget reflects such a balanced proposal, and we believe Congress should it enact it and cancel the sequester.

Section 317

The Centers for Disease Control takes one of the largest hits in the budget request, and especially concerning is the proposed reduction in the 317 immunization program. A report to this Committee from CDC estimates that this program is underfunded by hundreds of millions of dollars. Even with expanded coverage of the Affordable Care Act in 2014, over 20 million people will still be without insurance. Vaccination programs have been proven to be some of the most cost-effective approaches to preventing disease and reducing healthcare costs, and the children's vaccine programs are estimated to be a 10:1 savings as one example.

What is the rationale for cutting this program by $58 million or close to 10% when we are still one to two years away from expanded coverage? Will this reduction cut purchase grants or operational support for health departments?

Answer: The FY 2013 Budget includes funds for vaccine purchase to continue outreach to the hardest to serve populations, and critical immunization operations and infrastructure that supports national, state, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs $25 million towards continuation of the billables project, which allows public health departments to vaccinate and bill for fully-insured individuals in order to maintain Section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The FY 2013 Budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The Budget does not continue funding for one-time enhancements planned for FY 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan.

In 2012, $190 million from the Prevention and Public Health Fund will be transferred to the 317 immunization program. How will these funds be used and will those activities continue in 2013 at the same level of support?

Answer: In FY 2012, the Prevention and Public Health Fund will meet the needs of the Section 317 Immunization Program, as well as provide one-time resources for infrastructure enhancements in health IT, planning and implementation of public health billing systems, adult vaccination, and capacity for vaccinating school-age children. The FY 2013 Budget directs $25 million towards continued progress in the billables project, but eliminates these other one-time enhancements.

Number of Refugee Arrivals that the FY '13 Budget is Predicated On
Madam Secretary, as you may know, there are severe backlogs in processing refugee admissions because of a combination of new security requirements and the lack of coordination between security checks and non-security checks. This has impacted Iraqis and Somalis, most particularly. For example, close to 30,000 Iraqi refugees who have been approved to come to the United States are waiting for security clearances. The Administration is currently trying to expedite the process, which could result in the arrival of more refugees this year and in the next fiscal year.

How did Health and Human Services predict the number of expected FY 2013 refugee arrivals or the ORR budget? Also, has the predicted number of FY 2013 refugee arrivals that your budget is predicated on been coordinated with the Department of State, which bears the primary responsibility for making the refugee admissions recommendation to the President for his annual Presidential Determination?

Answer: The FY 2013 Refugee Resettlement request is based on the current (FY 2012) State Department refugee ceiling and on more recent information about actual FY 2012 arrivals. The request includes sufficient funds to serve 72,500 refugees; a 12% increase over the 65,000 refugees the State Department currently estimates will enter the U.S. in FY 2012.

Need for Emergency Housing Assistance for Refugees Resettled in the United States
Due to rising living costs, newly arriving refugees are finding it increasingly difficult to secure and maintain employment and housing. A number of federally funded programs administered by local refugee resettlement agencies assist refugees in securing employment and housing. These programs have been highly effective at helping refugees achieve self-sufficiency through employment.

However, refugees are only eligible for most benefits and services during their first eight months in the United States. In the current economic climate, it can take refugees longer than eight months to secure sustainable employment which will enable them to afford basic housing for themselves and their families. If this trend continues unchecked, we run the risk that more refugees will fall into a cycle of homelessness and poverty, which would burden state and local government.

What amount does ORR predict will be spent on emergency housing assistance in FY13 and how does this compare with the amount you are planning to spend in FY12?

Answer: The FY 2013 President's Budget request is intended to address many refugee needs, including the provision of up to eight months cash and medical assistance for newly arriving refugees. With respect to emergency housing, refugees can access a variety of homelessness prevention and assistance programs through the U.S. Department of Housing and Urban Development or state or county housing programs. HHS Refugee Resettlement funds have not been targeted to emergency housing, beyond the provision of cash assistance and some limited use of refugee social services funds. The FY 2011 and FY 2012 budget requests for refugee social services included an increase of $25 million for emergency services, including housing, but increases for that purpose were not included in that program's final funding levels.

Need for Case Management for Refugees Resettled in the United States
Case managers are critical to the integration and success of refugees in the United States. They not only assist refugees when they arrive, they are also the first connection refugees establish with this country. Part of their work is to ensure that basic needs are met, community orientation is completed, all documentation is secured, families are connected to services they are eligible for, and children are registered for school. They also have a central role in helping refugees obtain employment and work toward self-sufficiency.

As the United States continues to prioritize and welcome greater numbers of refugees with special needs, there is an increased need for these types of services to help refugees achieve self-sufficiency and integrate into their communities.

How much funding is included in your FY '13 budget for case management services for refugees who are resettled into the United States?

Answer: The Office of Refugee Resettlement (ORR) has long recognized the importance of case management for refugees and other arrivals. Although case management is a major focus of the Matching Grant program, and funds from other Refugee Resettlement programs may be used for this purpose, ORR does not provide specific amounts for case management or track funding spent for this purpose. The FY2011 and 2012 budget requests for refugee social services included increases for case management ($15 million), but increases for that purpose were not included in that program's final FY 2012 enacted level.

Inadequate Services for Unaccompanied Refugee Minors
Madam Secretary, ORR estimates that 1,850 children will be served hy the URM program in FY 2013, which would be an increase of 200 children in relation to FY 2012. Despite this projected it does not appear that ORR has built the capacity and program to assist all of the children eligible for the program. Advocates report that when they have addressed this shortage with ORR for additional sites for URM placements be opened, they report that ORR has been unresponsive.

What happens to children when there is no capacity in the URM program to serve them and what is ORR doing to expand its capacity to serve all of the vulnerable refugee and migrant children eligible for the URM program?

Answer: Under the Unaccompanied Refugee Minor (URM) program, arriving refugee minors, and certain unaccompanied alien children, are placed in foster care and receive the full range of assistance available to foster children in that state. Additional services provided to these children include case management, independent living skills training, English language training, career/college counseling, assistance adjusting immigration status, cultural activities, support for social integration, and cultural and religious preservation. All currently eligible children are served by this program. HHS estimates that 1,850 children will be eligible in FY 2013 and the FY 2013 President's Budget includes sufficient funds to support this number.

Funding Formula
It is my understanding that the allocation of refugee funding to States is primarily based upon arrivals over the past 12 months, and delays in the arrivals of certain populations (Iraqis, Iranians, Somalis) limits the resources available in the areas of the country that receive them.

How does ORR intend to reconcile this lack of funding to serve these needy refugees once their security clearances have been addressed?

Answer: Approximately two thirds of refugee funding is provided through the Transitional and Medical Services (TAMS) program which is the primary provider of services for newly arrived refugees. TAMS funds are distributed as reimbursement for services provided to refugees after their arrival. To achieve correct distribution, ORR monitors arrivals throughout the year, makes quarterly adjustments in the amount of funding provided, and adjusts funding to provide reimbursement for services provided in the previous fiscal year.

Services to Unaccompanied Alien Children
Madam Secretary, despite increases in the Office of Refugee Resettlement (ORR) budget for unaccompanied alien children in recent years, gaps in service to these vulnerable children remain. Specifically, increased appropriations for the Division of Children's Services (DCS) has led to staff increases in your Department. However, only a minority of children are receiving home assessments or follow-up services once they are released from ORR custody.

Can you inform the Subcommittee about how the Division of Children's Services (DCS) within ORR is spending this additional funding. How many children receiving home assessment and follow-up services will be increased due to these funds?

Answer: ORR is currently providing home assessments as required under the Trafficking Victims Protection and Reauthorization Act. Assuming 8,000 children in FY 2013, the President's Budget includes sufficient funding to continue to meet these requirements. However, in the first halfbeginning of FY 2012, the number of Unaccompanied Alien Children (UAC) that

has been referred to ORR care by the Department of Homeland Security has increased by over870% as compared to last year's levels. ORR is working diligently to develop capacity and place the extremely high numbers of children in appropriate facilities. During this period of influx, existing resources are strained and as a result, follow up services may be temporarily delayed.

The Impact of Delays in Issuing the New Trafficking Grants

Madam Secretary, in the recent awarding of new trafficking grants, there apparently was a lag between when the new agreement was required to be in place and when services were being provided by the new grantees. According to the new funding agreement, the new trafficking grantees were required to be operational within 10 days of the award, a requirement that was clearly not met.

As a result, local providers were forced to provide services during this period out of their own budgets, placing those providers in a difficult financial position and placing some in a position where they could not provide needed services to these victims. In fact, I've heard reports from some local providers that they are still—almost six months later—using their own funds to provide these services.

What steps were taken by the Department to ensure that all enrolled victims and victims pending certification continued to receive resources during the transition to the grantees?

Would you please comment on delay in the release of the funding announcement, the extended decision-making process, and the subsequent late start date for the new grantees in the recent grant process and the impact this delay may have had with recipients of these services?

Answer: The Department announced the funding opportunity last spring and awarded funds within fiscal year 2011 as planned. Funds were awarded without a break in services to victims of human trafficking with close to two weeks overlap in funding between the former contractor and the current service providers.

The Department is committed to ensuring that trafficking victims receive the high quality, comprehensive case management services that they need and to keeping trafficking victims as healthy and supported as possible as they re-take control over their own lives. To that end, the Department has taken several steps to oversee the transition of services from the previous contractor to the current service providers, including monitoring the number of clients enrolled for comprehensive case management services on a daily basis. The Department also facilitated interagency coordination at the local level by publicizing relevant contact information of current and former service providers and encouraging outreach to local agencies that previously provided services under the National Human Trafficking Victim Assistance Program. The Department also monitored the enrollment of sub-grantees on a daily basis to ensure the program's service capacity.

Grantees met the terms of the grant announcement which required successful applicants to demonstrate the capacity to respond to emergency requests for assistance and provide case management and referral services within ten calendar days. Grantees achieved this by

establishing toll-free numbers, hiring qualified staff members, creating single points-of-contact for each program, recruiting and training local sub-grantees and conducting outreach to local anti-trafficking taskforces and coalitions. Within the first two months of the program, each grantee enrolled clients for comprehensive case management and referral services and established key relationships with sub-grantees. In all, 107 victims of human trafficking received services during that two month period and 69 sub-grantees participated in the program, which is comparable to past levels of operation.

Reduction in Per Capita Services to Trafficking Victims

Madam Secretary, according to HHS documents released through the House Oversight Committee in December, the new trafficking grantees have been awarded a little over $4.25 million, which is what was included in the Funding Opportunity Announcement (FOA). According to the new Office of Refugee Resettlement (ORR) website, however, the total grants that bave been awarded equal about $2.5 million.

Is this discrepancy due to the long transition between USCCB and the new grantees becoming fully operational, delayed because of the review of the grant applications by political appointees of the department?

Have per capita services to victims been reduced as a result?

Have tbe number of victims declined sharply or are they falling through the cracks?

Answer: There is no discrepancy. The current grantees under the National Human Trafficking Victim Assistance Program were approved for funding over $4.25M. The information in the ORR website provides more details and shows the amount of funds that have been disbursed to the grantees to date. ORR is in the process of disbursing the balance of the approved funding amount. As such, services have not been reduced. The number of victims served has not declined; in fact, as of April 1st, the three current grantees were providing comprehensive case management services to 250 victims. Under the prior contract, the number of victims receiving case management services on September 30, 2011 was 188.

NIH Public Access Policy

Adopted in 2007, the National Institutes of Health's Public Access Policy requires that all research funded by NIH be published and available within a year of its completion to the public. Ultimately, public access to scientific results is not simply about allowing the public to read federally subsidized articles - it is about using these articles to solve problems, grow the economy, and create jobs. This goal requires cutting-edge search and analysis technologies, and the proper permission to apply that technology to the federally subsidized article.

How will HHS ensure scientists, the private sector and the government can continue to innovate and update these papers as technology evolves?

Answer: The papers we collect under the NIH public access policy are made available to the public without charge on PubMed Central (PMC), which is a full text archive maintained by the National Library of Medicine's National Center for Biotechnology Information (NCBI). NIH

uses three strategies to ensure that PMC and its papers continue to be a highly valuable and useful resource particularly as search analysis technologies and the science evolves:

1) Major private sector search engines (e.g. Google, Bing, etc.) are able to readily, accurately, and efficiently index papers so that users benefit from the continual improvement in these search tools in finding needed information.
2) PubMed Central is deeply integrated with other extensive NCBI resources that offer comprehensive bibliographic, DNA sequence, protein structure, genetic, chemical, and other health related information. The entire system continues to evolve along with the underlying science. The NCBI website employs the latest advances in search and retrieval technology for all data resources, providing users a wide range of modes for discovering useful publications and connecting the publications with additional scientific resources.

3) NCBI provides a programmable interface to its information resources that allow academic and private sector users to easily leverage NCBI systems and to integrate NIH-provided information with their own resources. In fact, 40% of the access to NCBI systems is made by other services that use this programmable interface.

These three strategies provide an incredibly diverse range of ways for users to discover relevant papers and associated scientific information, which generates very high levels of public use. Every weekday, seven hundred thousand users access PMC, retrieving over one and a half million articles. Based on internet addresses, an estimated 25% of users are from universities, 17% are from companies, and 40% from the general public.

AIDS Drug Assistance Program

Getting medications to people with HIV/AIDS who cannot afford them is critically important. I am concerned with the recent funding shortages in the Ryan White AIDS Drug Assistance Program (ADAP). Last September, there were 9,298 people on waiting lists. Currently, after some funding increases by the President and the Congress, the wait list is down to 3,809 in eleven states which is still too high.

How is the Administration addressing the ADAP funding crisis to make sure people are getting their medications? Do you believe the proposed increased to the program will fit the need?

Answer: The Budget targets funding to ensure that HIV-positive Americans get life-saving medications and are linked into community-based providers. This Budget has put forth an investment based on current waiting lists projections and with continued sufficient state contributions, these resources will enable all people living with HIV/AIDS who lack access to health care to obtain life-saving medications. This is consistent with the National HIV/AIDS Strategy (NHAS), which notes that success in reaching the goals is dependent on commitments from all parts of society.

Included in the Budget is $1 billion, an increase of $67 million, for AIDS drug assistance programs to provide life-saving and extending medications to 236,230 clients, an additional

18,906 people living with HIV/AIDS above FY 2012. In order to link people living with HIV/AIDS to care and remain on care, early intervention services are needed. The Budget also includes $236 million, an increase of $20 million, for Early Intervention Programs to provide direct grants to community-based clinics that offer primary care services for HIV testing and treatment to over 265,325 patients.

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[i] Taylor RS, Ashton KE, Moxham T, Hooper L, Ebrahim S. Reduced Dietary Salt for the Prevention of Cardiovascular Disease: A Meta-Analysis of Randomized Controlled Trials [Cochrane Review]. *Am J Hyperten.* 2011;24(8):843–853.

[ii] Garg R., Williams GH, Hurwitz S, Brown NJ, Hopkins PN, Adler GK. Low-Salt Diet Increases Insulin Resistance in Healthy Subjects, *Metabolism.* 2010;60(7):965-68. Epub 2010 Oct 30.

[iii] Stolarz-Skrzypek K, Kuznwtsova T, Thijs L, et al. Fatal and nonfatal outcomes, incidence of hypertension, and BP changes in relation to urinary sodium excretion. *JAMA.* 2011;305:1777-1785.

[iv] Graudal NA, Hubeck-Graudal T, Jürgens G. Effects of low-sodium diet vs. high-sodium diet on blood pressure, renin, aldosterone, catecholamines, cholesterol, and triglyceride (Cochrane Review). *Am J Hypertens* 2011;25:1–15.

[v] E.I. Ekinci, S. Clarke, M.C. Thomas, et al., *Dietary Salt Intake and Mortality in Patients With Type 2 Diabetes*, 34 Diabetes Care 703-09 (2011).

[vi] Thomas MC, Moran J, Forsblom C, Harjutsalo V, Thorn L, Ahola A, Wadén J, Tolonen N, Saraheimo M, Gordin D, Groop PH; for the FinnDiane Study Group, The Association between Dietary Sodium Intake, ESRD, and All-Cause Mortality in Patients With Type 1 Diabetes. Diabetes Care. 2011 Apr;34(4):861-866. Epub 2011 Feb 9.

[vii] O'Donnell MJ, Yusuf S, Mente A, Gao P, Mann JF, Teo K, McQueen M, Sleight P, Sharma AM, Dans A, Probstfield J, Schmieder RE. Urinary sodium and potassium excretion and risk of cardiovascular events. *JAMA.* 2011 Nov 23; 306(20):2229-38.

TUESDAY, MARCH 20, 2012.

BUDGET HEARING FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES—NIH

WITNESSES

FRANCIS S. COLLINS, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH (NIH)

THOMAS INSEL, M.D., ACTING DIRECTOR, NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS) AND DIRECTOR OF NATIONAL INSTITUTES OF MENTAL HEALTH (NIMH)

Mr. REHBERG. Good morning, and welcome. Let me begin by thanking the subcommittee for providing the leadership that resulted in an increase in Fiscal Year 2012 to support basic science. We recognize NIH's mission is to invest in basic biomedical research. We made policy choices to support the pipeline of investigators and the extramural basic biomedical infrastructure across the Nation.

The Fiscal Year 2012 Appropriations Act included a number of important items and statements of managers' provisions, and I expect NIH will ensure that both the letter and the spirit of this language is followed.

Specifically, our efforts provided a much needed base increase in specific language for the Clinical and Translational Science Awards (CTSA) and Institutional Development Awards (IDeA) programs.

We also continue support for the National Children's Study (NCS), which is of interest to both the ranking member and myself as co-founders of the Baby Caucus. The NCS is a necessary study of 100,000 children from birth to age 21. It aims to examine the effects of the environment on growth, development, and health of children across the United States.

The Fiscal Year 2013 budget request provides vaguely described changes to the study and an unanticipated reduction in the cost. A transparent discussion is needed to ensure the proposed changes do not undermine the scientific value of the study. As I think we all agree, it is important to finally gather a large body of scientific data which in the future can improve the health and well-being of our children.

I agree with one of the key NIH 2013 budget request themes, to invest in basic science. It is important, I believe, to support the historical level of 55 percent of NIH resources towards basic sciences. I would suggest that NIH develop a governance process towards this end; otherwise, the increased focus on translational research could squeeze out NIH's primary mission, that of basic science. We do not want to wake up in the future to find a NIH director without a stable full of science available for translation because we took our eye off the ball of basic science.

Another trend of concern is incremental decreases that continue to divert funds from the extramural to the intramural science programs. Again, I suggest NIH find a governance process to resume the historical balance of 10 percent for the intramural programs.

Finally, I cannot imagine supporting NIH's request to reduce the base of the IDeA program below the level of Fiscal '12. This program supports diversity, capacity building, basic science, and developing young investigators in 23 States for less than 1 percent of NIH's budget.

Today, we have expert NIH and outside witness panels to discuss issues related to NIH and the National Center for Advancing Translational Sciences. I believe we have provided NIH with a more focused authority to study steps in the therapeutic development process, consult with experts in academia, biotechnology, and the pharmaceutical industries to identify bottlenecks in the processes that are amenable to reengineering.

The specific mission of NCATS is to coordinate and develop resources, to leverage basic research, to support translational science, and develop partnerships in ways that do not create duplication, redundancy, and competition with the industry activities.

NCATS has authority to support clinical trials and infrastructure activities, in addition to a reasonable, but narrower, level of authority to take drugs into phase two clinical trials. Congress did not provide or envision NCATS or NIH to have authority to compete with industry or become a drug developing organization. I repeat, Congress did not provide or envision NCATS or NIH to have authority to compete with industry or become a drug developing organization. The focus of NIH and NCATS is to study the process and leverage basic science towards the goal of providing tools and methods to industry which can one day speed up drug development process.

I am looking forward to the discussion, but let me first ask my ranking member, Ms. DeLauro, if she has any comments before we turn to the panels.

Ms. DELAURO. Thank you very much, Mr. Chairman. I do have comments.

Also let me just personally thank you for inviting me to come up a few minutes early. Unfortunately I could not do that. I hope I will have an opportunity to get a chance to at least shake hands with everyone who is testifying this morning. I actually was on the phone with a staff member in our district office whose mother is struggling with cancer, and I think my last comment to her was, well, you know, maybe I will get on the phone and call the NIH. So, you are our touchstone. I mean that very, very sincerely, when it comes to illness and disease in this country.

And as we meet here to discuss the National Institutes of Health, the House is preparing to debate a budget plan for the upcoming fiscal year. The House majority is renewing its demands for more and more drastic cuts that, in my view, will harm medical research and many other priorities vital to our well-being and to our future.

What the NIH does, and the research it supports at universities, hospitals, and institutes across the country, is unquestionably important to each of us. It alleviates suffering. It saves lives. And so many of you know that I am a cancer survivor—26 years this

month. I am here because of the grace of God and because of biomedical research.

Just last year, researchers found that anomalies in a single gene were present in nearly all of the most common types of ovarian cancer, a finding that may lead to more effective diagnostics and treatments. That is but one example of why NIH is the gold standard for biomedical research, not only in the United States, but in the world.

Medical research at NIH and elsewhere has led to, among other things, dramatic reductions in death rates from heart disease and stroke, more effective treatments for HIV/AIDS, improved survival rates for cancer, and better ways of managing diabetes. That is why we came together in a bipartisan way to double the NIH budget nearly 15 years ago, and why members of this subcommittee on both sides have continued to support NIH funding, even in the face of budgetary constraints.

The work of NIH also brings substantial economic benefits. Every dollar in funding is estimated to result in more than $2 of business activity and economic impact. A report released yesterday found that NIH funding supports nearly half a million jobs in our country, and another study found that our investment in the human genome project created nearly $800 billion in economic growth.

I doubt that we would have had the wherewithal to invest in the human genome project a decade ago if the discussion in Washington, D.C. today had taken place then. And think of what we would be missing. Medical biotechnology industries fostered by this research, are among the keys to our future growth and world competitiveness of our economy, new technologies, and more personalized treatments to improve the health of Americans.

Despite these benefits, recent budget choices have shrunk NIH. Total funding for the NIH is now $86 million less than it was just two years ago, and that is without considering inflation, meaning that those same dollars are able to support even less research. When adjusted for increasing costs of medical research, the NIH appropriation has lost 5 percent of its purchasing power since 2010, and 16 percent since 2003.

NIH estimates that it will be able to support 767 fewer research project grants in 2012 than it did in 2010, and 2,700 fewer grants than in 2004. Ten years ago NIH was able to fund almost 1 out of every 3 applications for research grants. Now, that "success rate" is down to less than 1 in 5. The erosion of resources may just be the beginning as the majority party demands still more cuts to the programs that are funded in appropriations bills. It appears that the 2013 budget resolution walks away from the multi-year agreement negotiated last summer, and instead reduces the limit on overall appropriations down to roughly the level of 2011, that package which was passed in the form of H.R. 1.

If the funds available to this subcommittee decrease, it is hard to imagine that the NIH will not shrink along with that total. After all, the NIH is one-fifth of our bill. H.R. 1, which the majority now seems to want to repeat, would have cut the NIH by $1.6 billion.

Budget debates may be conducted using fake terms like "domestic discretionary spending," but in reality we are talking about things like NIH research that saves lives.

What is at stake is whether national investments in medical research will be continued and expanded or whether we will scale back these efforts, lose jobs, and cede leadership to other nations.

At today's hearing, Chairman Rehberg has asked the witnesses to focus particularly on the new National Center for Advancing Translational Science, and to address issues of possible overlap and duplication with the work of private industry. The purpose of that new center is to consolidate and focus NIH resources aimed at improving the science of translating research, and to better treatments and cures for patients. That is a critically important mission. It will be good to get an initial progress report.

Possible duplication with the private sector is an important issue to explore. But the most important question should be whether this new focus will help to speed cures, diagnostics, and treatments to patients.

We will hear from two distinguished panels this morning. The first consists of leaders from the NIH. The second has experts from the pharmaceutical, biotech industries, along with a leading research from a non-profit foundation that works to advance therapies for Parkinson's disease.

Welcome to each of you. I look forward to your testimony and to the questions that follow. Thank you very much. Thank you, Mr. Chairman.

Mr. REHBERG. Let me begin by thanking you, Ms. DeLauro, for your input in the hearings that we are going to have over the course of the next couple of days.

Ms. DELAURO. Thank you.

Mr. REHBERG. It was very important to hear your suggestions.

Ms. DELAURO. Appreciate it.

Mr. REHBERG. We were able to fit some of them in.

Ms. DELAURO. I know. I appreciate it. And this is one that is particularly important as you know.

INTRODUCTION OF WITNESSES

Mr. REHBERG. Great. I am going to introduce both panels first. And our first panel includes the one and only NIH director, Dr. Collins and the acting director of NCATS, Dr. Insel. Welcome. They will discuss what regulations, policies, and guidance are being established in Fiscal Year '12 within the NIH and NCATS governance system to ensure it does not compete with, duplicate, or invest in redundant activities in industry. See a theme developing in my statement?

I asked NIH to highlight how input from industry will be collected and evaluated to ensure NIH complies with the law. In addition, I hope NIH will discuss how the Fiscal Year '13 request ensures basic science is not negatively impacted, given its recent focus on NCATS. I will not repeat it. You got it.

Our second panel will discuss key hurdles observed with pharmaceutical development which hinder the advancement of translational science, and how NIH or NCATS can coordinate activities to leverage basic science in ways to improve how the phar-

maceutical industry can accelerate moving discoveries into treatments. We have three very distinguished witnesses in Dr. Roy Vagelos, former chairman/CEO of Merck and Company, Dr. Scott Koenig, M.D., Ph.D., president and CEO of MacroGenics, and Dr. Todd Sherer, Ph.D., CEO, of the Michael J Fox Foundation for Parkinson's Research.

I hope you will be able to stay for the second panel. I think that you indicated you were going to be able to do that. I appreciate that very much. It is always good to hear it one more time from an outside source.

So, Dr. Collins, the floor is yours.

DR. COLLINS' OPENING STATEMENT

Dr. COLLINS. Well, thank you, and good morning, Mr. Chairman, and members of the subcommittee. I am very pleased to present the President's Fiscal Year '13 budget request for the National Institutes of Health. And I must begin by thanking you, Mr. Chairman, for the $1 billion increase you proposed for NIH in your draft Fiscal Year '12 bill, and for the ultimate Fiscal Year '12 appropriation which maintained NIH's budget at the Fiscal Year '11 level.

We are also grateful for your leadership in creating this new National Center for Advancing Translational Sciences or NCATS.

In addition to Dr. Insel, who is sitting next to me, I would like to mention that Dr. Harold Varmus and Dr. Tony Fauci are also here, leaders of the National Cancer Institute and the National Institute of Allergy and Infectious Diseases, respectively.

This morning, I would like to highlight a few of NIH's many contributions to our Nation's health and its economy, as well as discuss NIH's commitment across this wide spectrum of basic and translational research.

Let us start with health. NIH funded research has prevented untold human suffering by enabling Americans to live longer, healthier, and more productive lives. These benefits include a 70 percent reduction in the death rate for heart disease and stroke over the last half century, a 40 percent decline in infant mortality in the past two decades, and much more.

And then there is the economy. As our Nation struggles to recover from a difficult period, it is worth pointing out that government investments in biomedical research are a terrific way to spur economic growth. Eighty-four percent of the NIH budget goes out in grants to researchers located in every one of our 50 States, and each dollar NIH sends out is estimated to return $2.21 to the local economy in just one year.

NIH supports approximately 432,000 high quality American jobs, and when our partnerships with the private sector are factored in, this rises to more than 8 million jobs.

Technological advances are driving rapid progress in medical research today. No less a futurist than Steve Jobs once said, "I think the biggest innovations of the 21st century will be the intersection of biology and technology." He was spot on. A striking example: The cost of sequencing a human genome, all of the DNA in our instruction book. Twelve years ago, it cost $400 million; five years ago, $10 million, today less than $8,000. And within the next year or two, a couple of U.S. companies plan to sell machines that se-

quence a genome in a single day for $1,000 or less. Those machines used to be the size of a phone booth. Here is one of them today. That is a DNA sequencing machine. This will revolutionize how doctors diagnose and treat diseases and will allow researchers to pursue previously unimaginable scientific questions.

Mr. Chairman, NIH is the leading supporter of basic biomedical research in the world, and this year has been the case for many years. Slightly more than half of NIH's budget will support this kind of fundamental research, which I understand is a major concern of yours, and I agree with that. There is no competition, though, between basic and applied research at NIH. I support basic research that makes possible a wide range of new biological discoveries, discoveries that in turn can then be translated into new strategies for diagnosing, treating, and preventing disease, and which, in turn, in a virtuous cycle triggers new ideas in basic research.

But there is much work to be done. Despite phenomenal progress in basic science, we still lack effective treatments for far too many diseases. And this translational pipeline to get there is long, 14 years on the average. And it is leaky.

A recent article in the Journal of Nature Reviews Drug Discovery found that despite huge and growing investments in research and development from both public and private sectors, the number of new drugs approved per billion dollars spent has fallen steadily since 1950. Bottlenecks continue to vex this process resulting in long development times, very high failure rates, and steep costs.

We need to re-engineer this pipeline, and that is why this new center, NCATS, is already working with industry in a complementary way to develop innovative ways to speed the flow of new therapies to patients.

Mr. Chairman, I have described the synergy between basic and translational research at NIH, but I would like to close with a story that ties these points together. As toddlers, twins Alexis and Noah Beery were diagnosed with a rare and devastating movement disorder called dystonia. Although they initially responded to empirical treatment, their symptoms reappeared and worsened as they entered their teenage years. Noah developed severe tremors in his hands. Even worse, his sister, Alexis, began falling frequently and had frightening episodes where she could not breathe.

Desperate for answers, doctors at Baylor College of Medicine sequenced the twins' genomes. The result? Discovery of a never before described genetic mutation affecting neuro transmitters in the brain. After being put on a new treatment regimen tailored to their unique genetic profile, the twins' symptoms began to improve within just two weeks.

I saw a video last night of the two of them doing tricks on a trampoline. In fact, Alexis' breathing is so much better today, she has joined her school's track team.

Now, while this story centers on two teens with a rare disease, this outcome carries a message of hope for all of us. It points directly to the promise that NIH research offers to patients of today and tomorrow.

So, thank you for this opportunity, Mr. Chairman, members of the subcommittee. I will be glad to answer your questions.

[Prepared statement and biography of Dr. Francis Collins follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Witness appearing before the
House Subcommittee on Labor-HHS-Education Appropriations

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

Good morning, Mr. Chairman and distinguished Members of the Subcommittee:

I am Francis S. Collins, M.D., Ph.D., and I am the Director of the National Institutes of Health (NIH). I have with me Thomas R. Insel, M.D., Director of the National Institute of Mental Health (NIMH), and the Acting Director of the new National Center for Advancing Translational Sciences (NCATS).

It is a great honor to appear before you today to present the Administration's fiscal year (FY) 2013 budget request for the NIH.

First, I would like to thank each of you for your continued support of NIH's mission to seek fundamental knowledge about the nature of living systems and to apply it in ways that enhance human health, lengthen life, and reduce suffering from illness and disability. In particular, I want to thank the Subcommittee for your support during deliberations about the FY 2012 budget, for the ultimate appropriation of $30.62 billion for NIH, and for the provisions that established NCATS.

NIH basic research and translational advances have prompted a revolution in the diagnosis, treatment, and prevention of disease. Biomedical research funded by NIH has prevented immeasurable human suffering and has yielded economic benefits as well, thanks to U.S. citizens living longer, healthier, and more productive lives. These benefits include:

- nearly 70 percent reduction in the death rate for coronary disease and stroke in the last half century;
- effective interventions for HIV/AIDS prevention and treatment, such that an AIDS-free generation may be within our grasp;
- nearly 30 percent decline over the last three decades in the age-standardized prevalence of chronic disability among American seniors;
- 40 percent decline in infant mortality over 20 years and better treatments for premature and low-weight births that result in increased infant survival, the prevention of cerebral palsy, and better developmental outcomes; and
- more than 150 FDA-approved drugs and vaccines, or new uses of existing drugs.[1]

[1] Stevens, A.J., *et al.*, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines." *N. Engl. J. Med.*, 364: 535-41, 2011

The Administration's FY 2013 budget request for NIH is $30.86 billion, which is the same overall program level as FY 2012. This proposed appropriation will enable us to spark innovation and invest in areas of extraordinary promise for medical science. We will also invest these resources wisely to encourage a vigorous workforce that is prepared to tackle major scientific and health challenges.

Within the Administration's FY 2013 budget, we will continue to protect and increase Research Project Grants (RPGs), NIH's fundamental funding mechanism for investigator-initiated research. NIH expects to support an estimated 9,415 new and competing RPGs in FY 2013, an increase of 672 above the estimate for FY 2012, with an average cost of about $431,000. For FY 2013, total RPGs are expected to number around 35,888.

To maximize funding for investigator-initiated grants, and to continue our support of first-time researchers, we propose to reduce budgets for non-competing RPGs by 1 percent from the FY 2012 level and to restrain growth in the average size of new awards. We will also no longer assume out-year inflationary increases for new and continuing grants. To nurture early career scientists, we will continue our efforts to ensure that the success rates for investigators submitting new R01 applications are the same whether the applicant is first-time or more experienced.

In FY 2013, we will also conduct an additional review of proposed awards to any principal investigator (PI) who already has NIH funding of $1.5 million or more in total annual costs, approximately 6 percent of PIs. This review will be conducted by each institute's advisory council. This is similar to a policy the National Institute of General Medical Sciences (NIGMS) has had since 1998, which will serve as a model for NIH. We recognize that some types of research, notably large complex clinical trials, routinely will trigger this review. We also know that some of our most productive investigators are leading significant research teams that require over $1.5 million to be sustained. This extra level of review will not be viewed as a cut-off point, but as an opportunity to apply additional scrutiny to be sure any added resources are justified by exceptional scientific promise.

Another significant change in the FY 2013 request is an 11 percent increase in the NCATS budget. The proposed budget includes an increase of $39.6 million for the Cures Acceleration Network (CAN), which received $10 million for start-up funding in FY 2012. CAN will fund initiatives to address scientific and technical challenges that impede translational research, and to advance the development of "high need cures" by accelerating the pace and reducing the time between research discovery and therapeutic treatment. This will include support for the Integrated Microsystems for Drug Screening Initiative, which will have graduated from receiving funding from the NIH Common Fund. In total, nearly half of the increase requested for NCATS will be used to transition programs from the Common Fund, allowing the Common Fund to support additional cross-cutting, trans-NIH programs.

Also of note, the FY 2013 NIGMS budget would decrease by $50.5 million, primarily due to not continuing the 21 percent increase that Congress provided in FY 2012 for the Institutional Development Awards program. The budget of the Office of the Director is also cut by 1.9 percent from FY 2012 enacted, reflecting a reduced request for the National Children's Study; we will implement alternative sampling approaches that will reduce costs and still achieve the ambitious objectives of the Study.

In FY 2013, the President is also proposing to spend $80 million from the Prevention and Public Health Fund to provide additional support for Alzheimer's research as part of the National Plan to Address Alzheimer's Disease. As many as 5.1 million Americans currently suffer from Alzheimer's disease, more than 280,000 more Americans will be diagnosed with the disease this year, and nearly 800 of our fellow citizens are diagnosed every day. By the year 2030, the last baby boomer will turn 65 and 7.7 million Americans over the age of 65 will have Alzheimer's disease.[2] Today, Alzheimer's and other dementias cost the United States economy more than $180 billion a year and if no cures and therapies are found, will cost the United States $1.1 trillion annually by 2050. The $80 million of new funding will support research with a strong focus on the prevention of Alzheimer's disease, including research to identify genes that cause this disease, to develop tests for high-risk individuals, and to identify possible targets for therapeutic development.

Having summarized the President's FY 2013 request for NIH, I'd like to discuss the continuum between fundamental research and translation by quoting the founder of Apple Computer, the late Steve Jobs. In his biography, Jobs is quoted as saying that a "silver lining" in his battle with pancreatic cancer was that his son Reed had been able to "spend a lot of time studying with some very good doctors." Jobs goes on to say that his son's enthusiasm for biomedical research:

. . . is exactly how I felt about computers when I was his age. I think the biggest innovations of the twenty-first century will be the intersection of biology and technology. A new era is beginning, just like the digital one was when I was his age.[3]

As I discuss NIH's commitment to basic and translational research, and our nation's new center for advancing translational sciences, please bear Jobs' words in mind: today technological advances are driving science. We need look no further than the cost of DNA sequencing to see this dynamic at work. The cost curve for sequencing is dropping at a breathtaking rate; sequencing speed has increased even faster than computer processing speed. What's more, the average cost of sequencing an entire genome has fallen from about $3 billion 12 years ago, to $10 million five years ago, to about $7,700 today. Two U.S. companies have recently announced that they are manufacturing machines that will sequence an individual's genome for approximately $1,000, and that the first such instruments will go on sale before year's end. Lower sequencing costs will likely revolutionize how clinicians diagnose and treat diseases and enable the research community to pursue previously unimaginable scientific questions.

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[2] Alzheimer's Association, 2011 Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia, Volume 7, Issue 2

[3] Isaakson, Walter, Steve Jobs (New York: Simon & Schuster, 2011) 539.

BALANCING BASIC AND APPLIED RESEARCH

NIH is the leading supporter of basic biomedical research in the world. Put plainly, if we don't fund basic research, most of this work would not get done, and it would be only a matter of time before this wellspring of new understanding and new therapies would dry up. NIH's funding for basic research is slightly over half (54 percent) of research funding, and this balance between basic and applied research has remained fairly constant over the past decade.

I also would like to address what may be a misconception about a competitive tension between basic and applied research at NIH. As our support of basic research has enabled new discoveries, NIH-funded scientists have always striven to turn the most compelling of them into medical advances. Basic discovery and the development of therapies go hand-in-hand at NIH. The two types of research have - and always will - exist together in a continuum. Today, Mr. Chairman, I would like to highlight just a few areas in which basic research advances are opening up new translational opportunities.

One fascinating area of basic research is the Human Microbiome Project, an initiative supported through the NIH Common Fund. This project is giving us wonderful insights into the sweeping range of bacteria that live on and in each of us, and is expanding our knowledge about the role of these microbial communities in health and disease. Recent scientific evidence suggests that changes in the composition and activity of the human microbiome may contribute to obesity, which may provide us with new ways of addressing this serious threat to our nation's health.

Another recent example emphasizes the "virtuous cycle" between basic and clinical research. The NIH Clinical Center has recently established a groundbreaking program that seeks to identify the cause of illnesses that have remained unsolved by other medical practitioners. Since the program started in 2008 some 1,700 people with undiagnosed conditions have been referred to Dr. Gahl, and more than 300 have been accepted for an initial week of consultations and testing. In the 15 to 20 percent of cases that we have successfully diagnosed, it has taken from a week to as long as two years to resolve. For example, a pair of sisters from Kentucky suffered from joint pain and mysterious calcification of the arteries in their extremities. Full evaluation and DNA sequencing led to the discovery of an entirely new genetic condition, where a previously unknown enzyme pathway in their arteries was blocked. This has led to a dramatic new understanding of how the large arteries in all of us maintain their normal health, with immediate research spinoffs in the basic and clinical arenas.

TRANSFORMING TRANSLATIONAL SCIENCE

The translation of basic biological discoveries into clinical applications is a complex process that involves a series of intricate steps. These steps range from the discovery of basic information about the causes of disease, an assessment of whether that information has the potential to lead to a clinical advance, the development and

optimization of therapeutics to test in human trials and, ultimately, the application of the approved therapy, device, or diagnostic in the real world. Drugs exist for only about 250 of the more than 4,400 conditions with defined molecular causes.[4] And it takes far too long and far too much money to get a new drug into our medicine cabinets. This is an old problem that cries out for new and creative solutions.

In the past, drug development was based on a short list of a few hundred targets, but with advances in technology, we are now able to identify thousands of new potential drug targets.[5] We can also study whole pathways, organ systems or even entire organisms rather than limiting the research to a single aspect of cell biology or physiology. Technologies such as large-scale sequencing, robotic high-throughput screening, and real-time imaging modalities uncover massive amounts of data that may one day lead to new therapies to prevent, treat, and possibly cure diseases. Many of the NIH Institutes are deeply engaged in these efforts. But we face serious engineering challenges. To put it simply, the current translational science framework pursued in both the public and private sectors, largely focused on individual projects on specific diseases, has not been fully able to utilize recent scientific advances to address the bottlenecks that lead to long development times, high failure rates, and high costs. NCATS is the catalyst we need to reengineer the discovery and development process.

To tackle this problem in a science-driven way, NIH proposed the creation of NCATS with the goal to develop and test innovative tools, technologies, and approaches that will enhance the development of drugs and diagnostics for application in all human diseases. NIH has the expertise and enthusiasm to tackle this as a scientific problem. By focusing on the development of innovative new methods for conducting translational science, as opposed to developing therapeutics themselves, NCATS can enable others to bring new medical products to patients in a highly efficient, cost-effective manner. In the four months since it was established, NCATS has already developed three new initiatives in partnership with industry, academia, and other government agencies.

In the first, NIH is working closely with several pharmaceutical companies to develop model agreements for a new pilot program to rescue failed drugs. Pharmaceutical companies have access to promising compounds that have been shown to be safe in humans, but that did not prove effective in treating the condition for which they were intended. Researchers are now learning that a compound that is a failure for one condition may help to treat another. To capitalize on this, NCATS is developing a pilot program in partnership with industry that will seek to crowdsource some of the most promising of these compounds to the brightest minds in science, an unprecedented opportunity for NIH-funded researchers and a new way to bridge academic science with industrial expertise.

Secondly, NCATS is partnering with the Defense Advanced Research Projects Agency (DARPA) to develop a chip that will mimic how humans respond to a drug.

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[4] Braun, *et al.*, "Emergence of orphan drugs in the United States: a quantitative assessment of the first 25 years." *Nature Rev Drug Discov.* 9(521), 2010; Online Mendelian Inheritance in Man, http://www.ncbi.nlm.nih.gov/omim/.

[5] Collins, F.S., "Reengineering Translational Science: The Time is Right." *Sci. Transl Med.*, 3(90):90cm17, 2011.

Scientists funded by NIH and DARPA will spend five years working closely with each other to place 10 diverse human tissues on a chip so that they will interact with drugs the same way that they do in living patients. By providing a better model to predict drug safety and efficacy, the most promising drug candidates can be identified more quickly and moved forward into development. The Food and Drug Administration will be heavily involved in an advisory capacity to ensure this research aligns with regulatory requirements.

In the third initiative, NCATS is working closely with industry to develop systematic ways to identify the most promising drug targets from the troves of data pouring out of basic research labs. To turn these discoveries into therapies, scientists in academia and industry need to be able to sift quickly and accurately through these data to identify the best targets. NCATS, along with industry partners, is taking the lead on developing a consortium that will strive to come up with the most streamlined ways to conduct target validation.

I want to emphasize that these and other initiatives within NCATS will provide resources and expertise to assist the basic research community in moving their discoveries to the next phase, as well as stimulate the basic research enterprise. For example, the Molecular Libraries and Imaging Program, originally implemented through the NIH Common Fund, has been successful in the development of chemical probes for basic and translational research. Many of these new probes have been, or are being, modified for use in the clinic, resulting in patent applications, licenses to pharmaceutical companies, and new therapeutic strategies.

In the months before NCATS was created by this Subcommittee, NIH engaged in an unprecedented outreach campaign to make sure that all stakeholders—including industry—had an opportunity to comment on the proposed Center. In addition to NIH's Scientific Management Review Board and Advisory Council to the Director, NIH consulted with the boards of the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Association, the R&D heads of pharmaceutical and biotechnology companies, and the investment banking and venture capital communities. In addition, NIH held a series of workshops with pharmaceutical and biotech firms to discuss drug rescue and repurposing, and target validation.

It is important to note that NCATS' work will assist *all* of NIH's Institutes and Centers in their translational and drug development efforts. NCATS will provide NIH Institutes and Centers the tools, methodology, and infrastructure necessary to speed new approaches to therapeutic treatments. The new Center also will work with other NIH Institutes and Centers to convene workshops with industry, non-profits, and other government agencies to explore critical translational areas and innovative public-private sector partnerships.

With the FY 2013 budget, NIH will pursue efforts to streamline and shorten the pathway from discovery to health through several new and ongoing initiatives and programs.

In conclusion, Mr. Chairman, we have never witnessed a time of greater promise for advances in medicine than right now. NIH is prepared to continue our long tradition of leading the world in the public support of biomedical research. Successful development of prevention strategies, diagnostics, and therapeutics will require bold investments in research across the spectrum from basic science to clinical trials, as well as new partnerships between the public and private sectors. With your support, we can promise continuing advances in medicine, creation of new economic opportunities, and stimulation of American global competitiveness in science, technology, and innovation.

This concludes my statement, Mr. Chairman and Member of the Subcommittee. I will be happy to answer any questions you may have.

Francis S. Collins, M.D., Ph.D
Director, National Institute of Health

Francis S. Collins, M.D., Ph.D. is the Director of the National Institutes of Health (NIH). In that role he oversees the work of the largest supporter of biomedical research in the world, spanning the spectrum from basic to clinical research.

Dr. Collins is a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the international Human Genome Project, which culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. He served as director of the National Human Genome Research Institute at the NIH from 1993-2008.

Before coming to the NIH, Dr. Collins was a Howard Hughes Medical Institute investigator at the University of Michigan. He is an elected member of the Institute of Medicine and the National Academy of Sciences, was awarded the Presidential Medal of Freedom in November 2007, and received the National Medal of Science in 2009.

Dr. INSEL. I do not have an opening statement. I think we can just get right into the discussion.

[Prepared statement and biography of Dr. Thomas R. Insel follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Witness appearing before the
House Subcommittee on Labor-HHS-Education Appropriations

Thomas R. Insel, M.D.
Acting Director, National Center for Advancing Translational Sciences
Director, National Institute of Mental Health

Mr. Chairman and Members of the Committee:

It is a privilege to present to you the President's Budget request for the newly established National Center for Advancing Translational Sciences (NCATS) for fiscal year (FY) 2013. The FY 2013 budget of $639,033,000 includes $64,320,000 over the comparable FY 2012 level of $574,713,000. We are thankful for your support for this new Center and look forward to sharing progress with you as the Center evolves.

Our mission is to catalyze the generation of innovative methods and technologies that enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. As such, NCATS will focus on addressing scientific and technical challenges in order to reduce, remove, or bypass significant hurdles across the continuum of translational research. These advances will enable others in both the public and private sectors to develop drugs and diagnostics more efficiently for any number of human diseases— ultimately accelerating the pace in which new therapeutics are delivered to the patients who need them.

FULFILLING OUR MISSION

In achieving its aims, NCATS activities will be guided by three important principles: 1) facilitate—not duplicate — other translational research activities supported by NIH; 2) complement — not compete with — efforts already underway in the private sector; and 3) reinforce—not reduce—NIH's commitment to basic research. These guiding principles underscore the role of NCATS as a catalytic hub for evidence-based research on the *process* of translating scientific discoveries into new diagnostics and therapeutics.

Key to the success of the NCATS mission is identifying, studying, and reducing significant bottlenecks in the process of translation, which will require extensive consultation with experts across disciplines and sectors. NIH held numerous workshops for stakeholders to solicit ideas for the NCATS research agenda. A working group of several NIH Institute and Center directors, including those most involved in translational research, clarified the need for a new effort focused on the discipline of translation, providing tools and resources that could facilitate research across NIH. A working group of the NIH Advisory Committee to the Director, comprised of experts from industry,

private equity firms, non-profits, and academia identified the need for NCATS to catalyze, invigorate and streamline translational sciences nationally and globally. Many areas of priority were identified, including research on biomarkers, predictive toxicity, target validation, regulatory science and de-risking the pipeline. The perspectives of both of these working groups are reflected in several of the NCATS initiatives being pursued, ensuring that NCATS is not duplicating other efforts at NIH or competing with efforts in industry.

NCATS is currently assembling an advisory structure comprising both the NCATS Advisory Council and the Cures Acceleration Network (CAN) Review Board. These individuals will span many sectors, from patient advocacy organizations to pharmaceutical industry and private equity firms, along with renowned experts in translational science and regulatory review.

CATALYZING INNOVATION IN CLINICAL RESEARCH

Re-engineering and accelerating the clinical research enterprise is a major priority for NCATS. The Clinical and Translational Science Awards (CTSAs), which represent nearly three quarters of the proposed NCATS budget, will lead our efforts to re-engineer and accelerate clinical research. Across the nation, CTSA institutions have been supporting first-in human trials for rare and common diseases; developing and testing innovative trial designs; and developing post-marketing clinical research. Since the first awards in 2006, the CTSAs have transformed clinical research in academic medical centers, creating new homes for translational science, integrating communities into the research process, and training a new generation of interdisciplinary clinical researchers. An external evaluation of the CTSA program has been conducted and offers constructive recommendations for ensuring that this highly valuable program is optimally leveraged and aligned with NCATS as we move forward.

To accelerate research, the CTSAs have developed innovative informatics tools, such as REDcap, a freely available tool for clinical study management and capture, and ResearchMatch, a free, secure, Web-based registry which now has over 20,000 volunteers for research studies and enables researchers to find the "right match" to participate in studies.

In 2013 we will be launching CTSA 2.0, the next phase of this program building on the successes of the past six years. While CTSA 1.0 established homes for translational research, CTSA 2.0 can create neighborhoods, networks of centers with shared resources to accelerate research on rare diseases and new therapeutics. Going forward, the CTSAs can have an even broader role on translational science, supporting the entire pipeline of development from bench to bedside, bedside to practice, and beyond practice to public health policy.

CATALYZING INNOVATION IN THERAPEUTICS

Drug development is expensive, slow, and failure prone. Approximately 90% of compounds that advance to clinical testing fail to reach the market.[1] While NCATS will not create an industrial drug development pipeline, it can experiment on the process, identifying solutions for specific problems in drug development.

For instance, one of the most common concerns we heard from industry, patient groups, and FDA, was the need for detecting toxicity early in the drug development process. Roughly one third of the failures of new medications can be attributed to toxicity not predicted from preclinical (animal or in vitro) studies.[2] NCATS is working with the Defense Advanced Research Project Agency (DARPA) and the FDA to design a chip composed of diverse human cells and tissues with read outs that can detect toxicity. This "tissue chip" should make drug safety assessments more accurate and even make them possible earlier in the translational pipeline. DARPA and NIH have committed approximately $70 million each over five years and FDA will provide guidance. The first applications were received in late January, 2012 and will be funded this year with partial support from the NIH Common Fund.

Aside from predicting toxicity, NCATS will be working on another innovation to speed medication development. Repositioning drugs that have not been approved (drug rescue) and drugs that are already approved (drug repurposing) are probably the most rapid and cost effective approaches to new therapies. As industry holds many of the assets and data required for efficient rescue and repurposing, many institutes at NIH have been interested in working with companies to access specific compounds. Rather than creating 26 different approaches, NCATS is working with industry to provide a single, comprehensive mechanism with several companies for drug rescuing. This will permit investigators and small businesses to apply for NIH funding to conduct research on new indications using compounds from industry-provided drug collections.

NCATS is also innovating the process of drug repurposing. Through the NCATS Pharmaceutical Collection, we have developed a comprehensive database of 3,800 approved and investigational drugs to permit NCATS to screen all existing medications for novel effects that might be therapeutic for a new indication. With this approach, we discovered that a drug approved for rheumatoid arthritis could be a novel treatment for leukemia. Rather than requiring 6 - 8 years for the usual preclinical research and development, we moved this approved compound into a leukemia trial (in a CTSA institution) within 9 months. Continued funding of this program in FY 2013 will contribute to the NIH effort of decreasing the time, cost, and attrition rate in therapeutic development, to bring more promising new therapies to the public.

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[1] Munos, Bernard. Lessons from 60 years of pharmaceutical innovation. *Nature Reviews Drug Discovery*, 8:959-968, (December 2009)

[2] Kola I, Landis J. Can the pharmaceutical industry reduce attrition rates? *Nature Reviews Drug Discovery*, 711-716 (August 2004)

SUPPORT FOR RARE AND NEGLECTED DISEASES

There are more than 6,000 rare diseases, affecting an estimated 25 million Americans. Fewer than 250 of these rare diseases have treatments, according to data from the Online Inheritance in Man Database, Orphanet, and FDA. It is clear that efforts need to be directed to increasing the number of treatments either through new or repurposed drugs. The Therapeutics for Rare and Neglected Diseases (TRND) program within NCATS develops treatments for rare diseases, with 20 projects currently underway. But TRND is not a typical drug development effort – the projects are selected as experiments on the pipeline of drug development. That is, each project is an attempt to re-engineer the process in addition to addressing a medical need. For instance, a project on sickle cell disease has introduced a new class of molecules not previously considered as medications for any disease. Moreover, the study of rare diseases, including many single gene disorders (Niemann-Pick Type C and Hereditary Inclusion Body Myopathy), is also giving us new insights into fundamental biology. This process, sometimes called reverse translation because it moves from "bedside to bench", is one of the ways that NCATS is reinforcing rather than reducing NIH's commitment to basic research.

INVESTING IN PEOPLE

NCATS fosters the training of clinicians and researchers in an environment of innovation and collaboration, encouraging the next generation of leaders in translational sciences. For example, the CTSAs are currently supporting over 900 trainees across a wide array of disciplines. NCATS will promote novel training mechanisms, such as drug development apprenticeships for early-stage investigators, and explore cross-training of physicians and scientists between industry and academia.

CONCLUSION

The creation of NCATS offers an exciting new opportunity for accelerating the development of new and more effective therapeutics and diagnostics; namely by approaching the process of translation as a scientific challenge. By encouraging biomedical researchers across the nation to experiment with new and innovative ways of improving these processes, our best and brightest can meet today's challenges head on. Moreover, the development of new tools and methodologies enable all sectors to participate in this arena, maximizing the likelihood of ensuring much needed products are actually available to those who need it the most - patients.

Thomas R. Insel, M.D.
Acting Director, National Center for Advancing Translational Sciences
Director, National Institute of Mental Health

In December 2011, Thomas R. Insel, MD was appointed as Acting Director for a new NIH Center, the National Center for Advancing Translational Sciences (NCATS). The mission of NCATS is to catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. Currently, many costly, time-consuming bottlenecks exist in the translational pipeline. Working in partnership with the public and private sectors, the Center will develop innovative ways to reduce, remove or bypass these bottlenecks. This will speed the delivery of new drugs, diagnostics and medical devices to patients.

Dr. Insel also serves as Director of the National Institute of Mental Health (NIMH), the component of the National Institutes of Health charged with generating the knowledge needed to understand, treat, and prevent mental disorders. His tenure at NIMH has been distinguished by groundbreaking findings in the areas of practical clinical trials, autism research, and the role of genetics in mental illnesses.

Dr. Insel has served on numerous academic, scientific, and professional committees and boards. He is a member of the Institute of Medicine, a fellow of the American College of Neuropsychopharmacology, and is a recipient of several awards, including the Outstanding Service Award from the U.S. Public Health Service and the 2010 La Fondation IPSEN Neuronal Plasticity Prize. Dr. Insel graduated from the combined B.A.-M.D. program at Boston University in 1974. He did his internship at Berkshire Medical Center, Pittsfield, Massachusetts, and his residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco.

IMPACT OF NCATS ON BASIC RESEARCH

Mr. REHBERG. I had better turn that on. Tell me about the governance within NIH and how you are going to maintain the 55 percent. How does this, first of all, the Fiscal Year '13 budget allow for that based upon the budgetary request? And then work into a little bit of NCATS.

It is no secret today. I did not necessarily like the way NCATS came about. I am a supporter. I encourage it. And yet this, you know, for those of us who are kindly more process oriented, the loosey-goosey attempt of creating an infrastructure without some meat on it always makes at least this member nervous. And so, convince me that you have got a plan that is going to, one, protect NIH extramural activities, maintain the 55 percent, and then as it relates to NCATS, how you intend to see this work over the course of the next few months.

Dr. COLLINS. Well, thank you for the question and for your support, Mr. Chairman.

And I know that the way in which NCATS came to this committee occurred in a fashion that did not have the number of details that you would have normally hoped to see during the regular budget process, and for that we apologize.

I will admit to being an impatient physician researcher charged with leading an organization, the largest supporter of biomedical research in the world, and feeling that an opportunity had arisen that could be, in fact, capitalized upon, and, therefore, was moving as swiftly as possible to see it come true. I guess trying to go against the idea that the government always moves slowly, we were maybe moving a little too fast for the pleasure of this committee. But I do think we can defend what has come forward now as part of NCATS in very strong ways.

To answer your question about the 55 percent for basic research, actually it is 54 percent, and in some years it has been 53 percent. But over the last 20 or 30 years, that percentage, as we define basic versus applied research, has remained essentially constant, and I do not expect that percentage to change in any significant way in the coming years because as you have rightly pointed out, NIH is the main supporter of basic biomedical research. These are the kinds of work that would not go on in the private sector generally because they will not connect to something that would result in a product. And so, it is our job to carry out that kind of research.

But at the same time, as I mentioned in the opening statement, we have the chance to capitalize on a deluge of basic science discoveries because they are pouring out of laboratories now, and to try to make sure that those do not remain for too long untouched.

And there is this valley of death, Mr. Chairman, which is commonly cited between some basic discoveries and ultimately arriving at a therapeutic or a diagnostic benefit where oftentimes things go to die. And if NIH can assist by the formation of this new center in identifying the bottlenecks that keep those successes from happening, then my sense is, and I get much encouragement from this from the private sector, and you may hear some of that in the second panel, that this is a role that we could play without skewing our investments in the favor of translational versus basic, but basi-

cally taking the translational efforts and putting them together under one center with the synergies that can create, with a hub that is created by that.

Most of the translational science that goes on at NIH is not going to be at NCATS. It is in our 27 institutes—the Cancer Institute, the Infectious Disease Institute. They have been in this space for a long time. That is why you can see so many vaccines, for instance, coming forward, so many new drugs where NIH played a major role.

But what we are trying to do is to identify the pipeline as the problem and to see how we could engineer that in a way that would break down these bottlenecks. That is what NCATS is about.

Dr. INSEL. If I can just add in one point of clarification to make sure we are all on the same page. This is indeed a new center, but with a very tiny exception. It is not new money. This does not shift the balance of anything because all of the programs that are in NCATS existed last year and the year before. What we are doing is building a new adjacency so they are now sitting next to each other interacting.

These were all funded before sitting at different parts of the NIH. The one exception is the 2 percent of our budget in NCATS that goes towards the Cures Acceleration Network. That is new, that $10 million program.

Mr. REHBERG. Ms. DeLauro.

CURES ACCELERATION NETWORK (CAN)

Ms. DELAURO. Thank you very much, Mr. Chairman, and I want to also welcome Dr. Varmus and Dr. Fauci. It is wonderful to see you.

Mr. Chairman, it is wonderful to have these folks here. This is one of the most exciting efforts that our government is engaged in and has been engaged in through the years. We are really the leaders in the world on this effort, and we have to maintain that standard. I am just so excited to have you here.

And I just will mention, with regard to the valley of death, it may be the place where drugs or some science goes to die. Quite frankly I am excited that you want to break the log jam of the bottlenecks because, quite frankly, the valley of death is for people who do not survive because we have not found a diagnostic or a therapy or a cure. That is really what the issue is. It is getting this so that somebody can take advantage of it and live. I mean, that is what we are about.

With that, your budget proposes a substantial increase in spending authority for the Cures Acceleration Network. That program received its first appropriation of $10 million in the 2012 bill. The budget proposes an increase to $50 million for 2013. Please tell us what the Cures Acceleration Network is intended to do, why you consider it important, and what more this proposed expansion would allow you to accomplish.

Dr. INSEL. Well, thank you for the question.

The Cures Acceleration Network is indeed the one new element within NCATS that was not there before. And this is the piece where we hope to be able to push forward an agenda that looks at fixing some of those log jams that you talked about.

When we have listened to industry about what are the main impediments to progress for them, we hear about two. One of them has to do with toxicity, that about a third of medications fail in trials because data about toxicity from animals does not predict what happens in the clinic.

Ms. DELAURO. Explain toxicity for a second. What is it?

Dr. INSEL. So, a drug that you develop for one indication has an adverse event, an adverse effect that keeps you from being able to develop it further. Sometimes we just cannot predict from what we have seen in animals. And so, that was one of the issues we heard.

The other one we heard about was what they call efficacy. It just does not work well enough. Those two together explain about two-thirds of the failures. And drugs fail 95 percent of the time when they get into the clinical pipeline. So, this is a big problem that all of us have a stake in.

What we hope to do with the Cures Acceleration Network is to establish a set of programs that can address this. One would be creating what we call tissue on a chip. These are human tissues now, not animal tissues, that would be able to screen compounds that are in early stage development to find out whether they do have toxicity. This is a lung, a human lung, on a chip that allows us with some efficiency for the first time to be able to look using what we call microfluidics. It is a technology recently online to go very quickly into looking into a whole series of different compounds to find out whether they are tolerated by human tissues, in this case lung tissue. We would like to do this across the board for human tissues to be able to predict toxicity in a dish. So, that is the kind of thing that we see the Cures Acceleration Network doing.

PERSONALIZED MEDICINE

Ms. DELAURO. How does that translate into an individual treatment? In other words, you are taking tissue, et cetera, from a lung. That is general. It is not an individual person or so forth. But in your route toward personalized medicine, what kind of application is——

Dr. INSEL. So, you are asking about the second piece——

Ms. DELAURO. Right.

Dr. INSEL. The things that are just more effective, and to get those into the pipeline. And the problem with that is often we just do not know enough about the biology of the diseases, the problem that we define as understanding the target you are going after. And that is really another important area for the Cures Acceleration Network is trying to figure out ways of working with many partners, because these are complex problems, to identify better partners, and then better targets, and also to think about ways that we can begin to use medications that might be there already developed for one indication and try to use them in a new one.

Ms. DELAURO. In another one.

Dr. INSEL. So, there are a lot of opportunities out there that are part of reengineering this pipeline.

Ms. DELAURO. My time is going to be up in a second, so I will yield back. No, that is fine. Thank you very much. Thank you.

Mr. REHBERG. Mr. Alexander.

IDEA PROGRAM

Mr. ALEXANDER. Thank you, Mr. Chairman, and good morning to you all.

Dr. Collins, my State of Louisiana is eligible for the National Institutes of Health Institutional Development Award IDeA program. It is a program which has played a significant role in building and strengthening biomedical research in the State.

The Louisiana IDeA Networks for Biomedical Research Excellence Program, called INBRE, has impacted 21 different colleges and universities within the State. It has enabled researchers to produce more than 100 journal publications and secure more than 80 additional research grants totaling $12 million in funding.

Louisiana INBRE has supported more than 650 students, staff, and faculty in biomedical research, as well as supporting summer research programs for students of which more than 100 have graduated and are now in graduate schools, and medical schools, and professional schools across the country.

At Louisiana Tech, INBRE has helped the institution recruit and retain talented junior faculty. From one grant alone, the researchers involved with the grant have now served on more than 16 NIH scientific review panels since obtaining support from the INBRE program.

The question is, why does it seem that the IDeA program is in a low priority as evidenced by the $51 million cut recommended for the program in the NIH budget?

Dr. COLLINS. So, Congressman, thank you for the question.

We are enthusiastic about the IDeA program, and as you pointed out, in the State of Louisiana and some other States represented here at the table. Montana, for instance, Idaho. This program has been a way in which NIH can support individual investigators at institutions in States that have not had the same tradition of research intensive universities that some States have. Those 23 IDeA States do, in fact, receive the support for this enterprise through a number of programs, and you have mentioned the INBRE program, which is an IDeA network for biomedical research excellence, and the COBRE programs, which are also centers of biomedical research excellence.

We were grateful for the additional increment of funds for the IDeA program in the Fiscal Year '12 budget, and we are following what was the sense of the Congress in terms of using those funds to fund two new centers for translational research as well as an additional set of eight COBRE centers with that additional funding.

But our understanding of the way in which this increment, you know, could be utilized was this was a much needed, one-time boost. And given the tightness of the budget in Fiscal Year '13 for many other areas, we, therefore, in the President's budget see that the funds for IDeA have been reduced roughly back to where they were in Fiscal Year '11.

I promise you the Fiscal Year '12 dollars will be spent. But considering the number of other pressures on the system, including the fact that investigators anywhere in our portfolio have seen the lowest success rates ever, and Congresswoman DeLauro mentioned those numbers, we felt that this was the most reasonable way to

balance. And that is how the President's budget lays out the plan for IDeA.

Mr. ALEXANDER. It has also been brought to my attention, of course, that the groups of IDeA researchers have sought to meet with you since you became the NIH director. They have met with NIH directors in the past. To this date, they have not been given a meeting. Can you help us understand why?

Dr. COLLINS. So, the IDeA program moved as part of the changes in structure of NIH in Fiscal Year '12 from where they had been located in the National Center for Research Resources, into the National Institute for General Medical Sciences (NIGMS).

I am not aware whether they have made a plea to meet with the director of NIGMS, Dr. Judith Greenberg, but I will say here in front of this committee, I would be glad to meet with the leaders of the IDeA program and discuss their concerns.

Mr. ALEXANDER. And at some point we would like to invite you to the State of Louisiana to look at some of the work going on there. Thank you.

Dr. COLLINS. You have a fine State, and I would enjoy the experience.

Mr. ALEXANDER. Thank you, Mr. Chairman.

INTENT OF IDEA FUNDING

Mr. REHBERG. If, Mr. Alexander will yield for a moment. Dr. Collins, we did not suggest in the Fiscal Year '12 that these were 1-year funds. We suggested that each of the programs be at 50 percent. So, I guess I do not understand the hesitation or the confusion or at least the difference, I think, of answers as I understand it.

Dr. COLLINS. Well, again, I believe in the President's budget. The proposal was that the dollars for IDeA in Fiscal Year '12, much appreciated as they were, were treated in the President's budget as a one-time addition to that program, not as a change in the base.

Mr. REHBERG. Not in our—excuse me, not in our Fiscal Year '12 budget. Not as we sent it out of here. It might have been in the President's suggested budget or his budget request, but that is not the way it went out of here as a one-time allocation. It was 50 percent in each program.

Dr. COLLINS. I am not sure I understand the 50 percent.

Mr. REHBERG. Identified for each program as opposed to being a one-time allocation, so it was an ongoing opportunity within the various programs.

Dr. COLLINS. Well, again, I think that is why were are here talking about Fiscal Year '13 is to figure out what the Congress' intentions would be going forward with the IDeA program. I guess I am here to represent what the President's budget put forward, which was an interpretation that this was a one-time allocation and not an adjustment in the base.

Mr. REHBERG. Okay. Ms. Roybal-Allard.

COMMUNITY BASED ORGANIZATIONS AS RESEARCH PARTNERS

Ms. ROYBAL-ALLARD. Dr. Collins, as we increasingly look to NIH investments in clinical and translational research, the engagement

of communities and partners in NIH research is essential to advancing NIH research investments.

As more community based organizations enter into research partnerships with NIH funded academic institutions, and initiate and conduct research, there is an increased need for NIH to provide them with direct support for research capacity building and research infrastructure.

Unfortunately, the current funding mechanisms and peer review processes at NIH are designed to support academic institutions, even if technically CBOs are among the organizations eligible to submit applications.

What funds are you requesting in the NIH 2013 budget to directly support the research capacity building and research infrastructure needed in community based organizations?

Dr. COLLINS. Well, thank you, Congresswoman, for the question, and we certainly agree that there is a great deal of strength in community based organizations both in terms of the services that they provide and the research opportunities that they can conduct.

I think a major area where we see this happening and have been gradually supporting in an increasing way is through the Network of Clinical and Translational Science Awards, the CTSAs. This is NIH's most major investment in clinical research now amounting to almost $500 million supporting 60 centers across the country.

And as part of those centers, community outreach is a component of their activities, especially urging them to link up with community organizations in their own geographic area where they will know them the best and try to build those networks of research capacity.

The CTSAs have actually moved to the National Center for Advancing Translational Sciences, so I will ask Dr. Insel to say a word about the CTSAs and the plans we have for them now because it is a moment of specific opportunity.

Dr. INSEL. Well, again, let me emphasize that for NCATS, for this new center that we are here to discuss, that we are talking largely about drug development. Eighty percent of our budget is the CTSA program, these 60 centers around the country that are, as Dr. Collins said, our largest investment in clinical research in this arena. So, those have had as part of their remit over the last five years, they are about five years old now as a program, the increasing engagement of communities, not only as a source of patient volunteers or research volunteers, but increasingly to get them in at the front end to help define what the research problems need to be and to bring them in as a full partner. And that has been one of the great successes of the CTSA program, one that we hope to leverage in the next five years as we go forward.

PANCREATIC CANCER: LONG-TERM STRATEGY

Ms. ROYBAL-ALLARD. Okay. I would like to move on to another subject that has been of a great deal of concern to me, and that is the fact that while the survival rates for many cancers are steadily improving, in some cases nearly 70 percent, the survival rate for pancreatic cancer, one of the most lethal forms of cancer, is only about 6 percent. And after submitting report language for many years, I was pleased that NCI finally released an action plan for

investing in pancreatic cancer research. However, as I understand it, it was disappointing that the action plan is mostly a summary of research that is already under way.

So, when can we expect to see a long-term research strategy for pancreatic cancer that establishes concrete objectives for the future and sets a goal of increasing the 5-year survival rate?

Dr. COLLINS. Congresswoman, I certainly share with you the sense of urgency about dealing with this very, very serious malignancy with currently 5-year survival rates that are lower than most other cancers.

There are two areas that perhaps are particularly exciting to contemplate right now to do something about this. First of all, pancreatic cancer clearly is diagnosed in general after it has been present for a very long time. Estimates are probably 20 years from the time the cancer starts until it is actually recognized, in part because it arises in a part of the body that is very far away from detection by the usual means.

If we had better means of detection of this disease early on, that would clearly make a huge difference. And right now, we do not have for pancreatic cancer those kinds of measures, and that is a big priority for research right now.

But furthermore, we do need to understand at the DNA level what is driving a good cell to go bad and become a malignant pancreatic cancer cell.

The Cancer Genome Atlas, which is this very bold initiative of the Cancer Institute and the Genome Institute, has pancreatic cancer on the list of cancers that are being unraveled in unprecedented detail, revealing what exactly is going on in those cells and revealing in the process new potential targets for therapy that might be much more successful in terms of curing this disease than in the current approaches which depend on chemotherapy.

Mr. REHBERG. Dr. Simpson.

NCATS

Mr. SIMPSON. Thank you, Mr. Chairman. I had two of my favorite hearings this morning, my favorite institutions, NIH and the Smithsonian down in my committee. So, I am glad I could make it up to it.

But NIH, as I have often said, is one of the best kept secrets in Washington. That is also one of the bad news stories in that the public needs to know what NIH does, and how we get that message out to the general public is some debate we have had over the last several years.

But I think as I listen to everybody on this panel, nobody disagrees with what we are doing with NCATS. That is a good direction that we ought to hit. But as I listen to people on the panel and to the general public, there is concern that it is going to take resources away from what has traditionally been used, as an example, the IDeA program and other things. And so, I get questions submitted to me that, you know, can you ensure the committee that the continued development of NCATS will not take resources away from other basic science initiatives, or hamper programs like IDeA? And can you detail how the National Center for Advancing Translational Science plans to engage all of the NIH institutes and

centers and the opportunities it puts forward particularly given that they were all tapped to contribute to the formation of this new center?

I think that is the main concern here is that any time you start something new, people wonder where you are going to get it, particularly in these budget times, and they are worried that it is going to come out of what they have been doing in the past, which we all agree with also.

Dr. COLLINS. So, maybe I will start and Tom may want to add. In the discussion about NCATS, this did not happen sort of overnight in a vacuum. So, basically going back now two years, the notion of whether NIH would benefit and whether the public would benefit from a hub for this sort of translational activity, even though there is a great deal of this work already going on the Institutes, was brought forward to our scientific management review board, a very distinguished group of experts. And they deliberated and took testimony and talked to lots of people and ultimately recommended that we should do this.

That then led to numerous other consultations, including, of course, with all the institute directors at NIH. And there was a lot of shaping of the program that went on during those months, and a very beneficial shaping it was. And now I think it is fair to say the NIH as a family is supportive of this enterprise and excited about it, not that it is going to compete with things that the other institutes are doing very well already, but providing particularly this focus on bottlenecks in the translational process, which otherwise would not get attention.

We consulted also with people in the private sector, distinguished leaders and pharma biotech venture capital in a working group that was put together. They came forward. Very enthusiastic in support of what this could do.

But we recognize that resources are tight; they are terribly tight. And so, the way in which NCATS came into being on December 23rd, as you heard from Dr. Insel, was largely to take programs already funded through other parts of NIH and bring them together, providing new synergies that were not there before.

The amount of new funds going to NCATS is a very small amount indeed, some bits of it in Fiscal Year '13, which Tom mentioned a minute ago. But we are trying to be very careful about this. We believe that we could do a lot with modest resources at this point simply by doing the focus on the bottlenecks, the way an engineer would do in a way that has not been possible, and by working with the private sector and making sure we are building on those kinds of relationships in new ways. And we are very vigorously involved in those kinds of workshops, and planning processes, and steering committees that have come together because of NCATS' existence providing the nucleus for it to do so.

Mr. SIMPSON. But certainly you can understand how people that are involved in other parts of NIH and have other interests, such as the IDeA program and stuff, when they see a proposal that reduces the IDeA budget by $15 and a half million and the development of NCATS, they look at it that is where they got the money.

Dr. COLLINS. Well, I really would like to speak to that because that is not the sort of connected lines there is any sense at all. We

are, of course, dealing with tight resources. You heard that effectively we have lost about 18 percent of our buying power since 2003.

I have to tell you the thing that wakes me up in the middle of the night, Doctor, is the realization that there is wonderful science that could get done, and that we have to make very tough decisions about what will get done because we do not have the resources to support all the great ideas, all the great investigators.

And so, it is constantly a struggle, but it is a struggle that involves some very bright, thoughtful, visionary minds in an ongoing process, practically weekly, trying to decide how should we set those priorities. I do not think we are perfect, but I think we do get the inputs that you would want to see us get in making those decisions.

Mr. SIMPSON. Thank you.

Mr. REHBERG. It is the chair's intent to have a second round before I recognize Ms. Lummis. But we will quit this segment at 11:30, so do not feel compelled to ask a second question if you do not want to.

Ms. Lummis.

IDEA

Ms. LUMMIS. Well, thank you, Mr. Chairman. I can see that this is a popular topic because I want to focus on IDeA as well.

I used to sit on my State's EPSCoR Committee, and the proposals that came through us that we vetted and referred on to NIH were truly remarkable at the University of Wyoming. So, again, if I am emphatically reinforcing things that are previously said, excuse my redundancy.

Have you ever visited one of these IDeA programs at a land grant school?

Dr. COLLINS. I have not personally since I became NIH director, but I have in the past when I was directing the Genome Institute.

Ms. LUMMIS. Okay. I would sure encourage you to do so. And if I could be so bold, I would recommend the University of Wyoming Center for Neuroscience. [Laughter.]

Dr. COLLINS. And your colleagues might say Montana, or I would say Idaho.

Ms. LUMMIS. Yeah. You could make a intermountain tour that we would be happy to accommodate.

Dr. COLLINS. And Louisiana, we got to get Louisiana in there, though, so we got to——

Ms. LUMMIS. Well, and that can be the icing on the cake.

The President proposes, what, $225.5 million for IDeA, that is a $50 million reduction, in order to fund other research priorities. What are those other priorities that would be higher research priorities than the ones you are receiving through the IDeA program?

Dr. COLLINS. Well, again, Congresswoman, NIH is a big fan of the IDeA program. I agree with you. We get wonderful proposals. We see wonderful science being conducted. But we see that across our portfolio and many other programs as well.

I think the fundamental area where there seems to be some friction or misunderstanding or difference of opinion is whether, in

fact, faced with the circumstance where the resources are so tight for everything, whether we could sustain——

Ms. LUMMIS. And I apologize for interrupting, but I would like you to direct your specifically your proposal to seek a $64 million increase for NCATS, which is a new program, and an almost $40 million increase for Cures Acceleration Network, which is another new program. So, that is where I would like you to focus your response.

Dr. COLLINS. Again, I would not want you to see a direct connection between what decisions were made in the President's budget about the IDeA program and about NCATS. Those are not the same dollars that just got moved from one box to the other. This is part of a big overall plan to try to figure out where the scientific opportunities are most pressing.

Ms. LUMMIS. But it does cut one place and add another, one of which is a new program. And maybe it is not exactly the same dollars, but, you know, dollars are dollars, and they are all borrowed money. So, we are just looking, since we are borrowing this money from China and Saudi Arabia, Japan, let us find out where to put it.

Dr. COLLINS. So, the dollars that go into the Cures Acceleration Network, that is actually part of NCATS, so that $40 million is part of the $60 that you mentioned. Those are not separate buckets. Cures Acceleration Network is a program within the National Center for Advancing Translational Sciences.

Congresswoman, that program aims to take advantage of an exceptional moment in history. If you look at the 4,000 rare diseases that currently exists, there are only treatments for 250 of those. Twenty-six million people in this country are affected with one of those rare diseases, and we see an opportunity to do something about that in a way we could not have four or five years ago. That is the motivation for this center. I would not be a responsible director of the NIH if I did not respond to that opportunity.

Ms. LUMMIS. Thank you, Mr. Chairman. I yield back.

HEALTH ECONOMICS

Mr. REHBERG. Thank you. We will start round two, but we are going to shorten the time to three minutes apiece so that we all have an opportunity to do it.

And in relation to funding and such, as I was going through the budget book, one of the questions I asked is what is the Common Fund, and I got a pretty good explanation of it. But I was aware of an awards presentation that was made in Fiscal 2011 having to do with about $2 and half million coming from that, which centered in on economics. And, you know, we had this whole conversation about basic science and all the various grants, and so I asked staff, of the $2 and a half million that was given in 2011 for economics studies, how many grants would that equate into. And we came up with 6 additional grants.

I guess the question is, why are you even involved in the economics? And just looking at it, one of them is, and it has been an issue that I have been intimately involved in, is the Class Act. Now, the President suspended the Class Act, and yet there is still a grant going out for the purposes of sending the Class Act as it relates to

the economics within the health care provision. And I just wrote some notes.

Let us see here. Another category of research is titled integrating comparative effectiveness research finding into care delivery through economic incentives. So, I guess the question is, first of all, why are you involved in economics when we have hundreds of Federal agencies that deal with that. And as it relates to the President's health care reform legislation or act, why not take the money and put it into the grants and the basic sciences as opposed to using this, I do not want to call it a slush fund, but essentially every director has one, and you do. Why are you involved in the economics of health care anyhow as an institute?

Dr. COLLINS. So, Mr. Chairman, I will probably have to respond to the record about the specifics of the two grants that you mentioned because I am not familiar with the details.

The Common Fund, I would say, maybe "slush fund" is not the term I would have chosen. It is our venture capital space, and it was very much advocated for by my predecessor, Dr. Zerhouni, and then became a reality in the NIH Reauthorization Act passed by this Congress in 2006. It is where we try to support research that no single institute would be able to do.

Mr. REHBERG. But this is not research. This is an economic study——

Dr. COLLINS. Well, it is research trying to understand——

Mr. REHBERG. What I am talking about.

Dr. COLLINS. Again, I am not sure I can respond about the specifics of one or two grants. The overall program in health economics is an effort on the part of NIH to understand particularly what are the economic benefits of the research that we conduct. We are asked oftentimes, including by the Congress, what are you doing in terms of being able to support the economy, jobs, and so on. And we have not always been confident we had sophisticated answers to that, and this part of a program to try to figure out whether, in fact, what we are doing is maximizing the taxpayer's investment.

I do not know about those two grants, but that was the overall plan behind the fund.

Mr. REHBERG. But at that time there were $2 and a half million worth of grants given in that year, and I would like to have an explanation because it is something I am going to be looking at as chairman——

Dr. COLLINS. I would be happy to provide that for the record.

Mr. REHBERG. As to whether that is an appropriate role for the NIH as opposed to others looking into the same issue.

Dr. COLLINS. I would be happy to provide that.

Mr. REHBERG. Thank you. Ms. DeLauro.

SUPPORT FOR YOUNG RESEARCHERS

Ms. DELAURO. Thank you, Mr. Chairman. Just a quick comment.

Fifteen years ago, this subcommittee made a determination on a bipartisan basis to double the amount of money that went to the NIH to specifically do the kinds of things that would lead us to, you know, to hold on to our cutting edge in terms of research—and both

basic research and applied efforts. So, that ought to be our goal again with this subcommittee.

Let me try to get in two quick questions for you, Dr. Collins. I will not go through explanation here. What would be the—well, for young researchers, what are your chances of winning a grant from the NIH these days? How does it compare to your chances 10 years ago? What has happened to the average age of researchers typically? And when they receive their first grant as an independent investigator? We are always concerned about getting new, bright young minds into this effort. What is the status of that effort? And what would be the effect on the biomedical research conducted and sponsored by NIH if across the board cuts in the realm of 8 to 9 percentage range were to occur in 2013?

Dr. COLLINS. Very quickly.

Ms. DELAURO. Young researchers.

[The information follows:]

House Subcommittee on Labor-HHS-Education Appropriations
The National Institutes of Health (NIH)
Office of the Director (OD)
Common Fund Health Economics Program

Overview: The Common Fund's Health Economics program aims to support research on how specific features of the structure or organization of health care delivery organizations and reimbursement systems influence how health care technologies are adopted and combined by health care providers, how they are applied or used for specific patients, and how those features could be modified to enhance efficiency. It uses past, current, and planned features of health care systems as the experimental cases for study. This program was launched in FY 2010 to support investigator-initiated peer-reviewed projects. The goal of the program is to ensure that NIH investment in fundamental research is effectively translated through health care systems into improved health.

Why is the Common Fund supporting Health Economics?

The NIH is continually asked for data to show how NIH-funded research improves the quality or duration of life; however, this is not always available. Moreover, data addressing uptake of research results - factors that either facilitate uptake or impede it and ways in which the information is applied - are scarce. The Common Fund Health Economics Program is intended to elucidate economic factors that contribute to the uptake of research results. It is also intended to address the economic benefit of improved health that results from the application of NIH-funded research. These questions are relevant to all Institutes and Centers (ICs), a criterion for Common Fund Programs.

Why is the Health Economics Program supporting research on the CLASS Act when it's been suspended?

The CLASS Act has been suspended, but the need for American families to finance long-term care remains a growing concern. Even if the CLASS Act had never passed, there would be reason for NIH to solicit research on who is willing to pay for long-term care (LTC) insurance and at what cost, and who is willing to supply LTC insurance with varying characteristics and at varying prices. LTC is among the biggest financial risks facing the elderly, disabled, as well as those who support them, and adequacy of the provision of LTC is a major determinant of health and well-being for the chronically ill and frail elderly. There are five grants on LTC in the Common Fund program, and they deal more generally with the market for LTC insurance rather than with specific features unique to the CLASS program. The abstracts written prior to the suspension in some cases mention that the study findings will be useful in implementing CLASS, but the research is relevant to supply of and demand for LTC insurance under other auspices; the value of the research is not diminished by the suspension of CLASS.

Why is NIH doing research in Health Economics? Isn't this in the mission of other Federal Agencies?

Improving health by studying the whole process, "bench to bedside", is a goal shared with

other Health and Human Services (HHS) agencies. In designing this program, NIH worked with both the Agency for Healthcare and Research Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to define a unique contribution using investigator-initiated peer-reviewed research to discover economic features of health care systems that can be used to translate research into health.

AHRQ has concentrated funding in some defined areas, including health IT, patient safety, and quality improvement. NIH research in health economics focuses on expanding fundamental knowledge about the system, not directly at producing the quality and patient safety improvements and practice guidelines at the core of AHRQ's mission.

CMS generally issues calls for demonstration projects and evaluation of existing programs. NIH does not duplicate these evaluation efforts, but instead funds investigator-initiated grants on fundamental and cross-cutting topics, such as the behavioral responses of providers, patients, and families to changed incentives and technology.

The distinctive NIH role is to fund investigator-initiated research judged to be of high scientific value and relevance to program goals. Rather than specify in detail what contractors, states, or health plans are to do, and then issue contracts to evaluate it - as a Medicare or Medicaid waiver does - NIH Funding Opportunity Announcements specify research goals, and then invite researchers from across the nation to devise ways to achieve the goals. This approach is a useful adjunct to the more programmatic goals of CMS and other operating divisions - it allows NIH to tap the creativity of researchers. The new initiatives of the Center for Medicare and Medicaid Innovations (CMMI) cover a broader range of issues within the U.S. health care system and may focus on broad delivery system reform. While this may present areas of overlap, NIH and CMS staff have met several times to discuss CMMI initiatives to avoid duplication.

More Detailed Background on Specific Grants

The $2.5 million cited in 2011 supports eight grants in the area of Long Term Care and the Integration of Comparative Effectiveness Research into Care Delivery. There are five grants on Long Term Care in the Common Fund program and they are generally focused on the market for LTC insurance rather than the CLASS program narrowly defined. The abstracts, in some cases, mention that the study findings will be useful in implementing CLASS, but that aspect generally is not central to the research goals nor is the value of the research diminished by the suspension of CLASS.

One of the grant abstracts (Konetzka, 1R01AG041108-01) makes the point well: "Regardless of the eventual fate or form of CLASS, the projected demographics of long- term care use and the associated strain on government budgets point to a more and more urgent need to answer these questions" [about the market for LTC insurance].

Webb (1ROIAG041105-01) has several aims: to develop an economic model for how households make decisions on saving and long-term care insurance; to solve an intertemporal optimization problem (that is, an economic problem in which a consumer must choose the best among several courses of action now, in the face of uncertainty about the values in future periods of many of the variables affecting choice) in order to estimate the optimal amount consumers would pay for LTC insurance; and to analyze the ability of insurance carriers to meet demand for long-term care. Another aim was to examine the ways in which households are likely to respond to the specific features of the long-term care insurance program proposed in the CLASS Act. However, since CLASS has been suspended, this aim is being refocused to model take-up of plans, however financed, with varying coverage, benefit amounts, and premiums. The other specific aims are unaffected.

Similarly, Hurd (1ROIAG041116-01) will simulate the effects of various public policies on the market for LTC insurance, of which CLASS was one. The model under development is useful without CLASS because it was not the central focus of the grant. Hurd will examine the economic reasons why the market for LTC insurance is not fully developed (that is, the range of products offered to consumers is very limited and price competition is not working to "clear" the market). Hurd plans to build life-cycle economic models for consumer spending that will integrate components such as out-of- pocket spending on health care, LTC in nursing homes, and health and life insurance, taking into account all financial resources available to households. The reason complex models are needed (rather than a simple one-sector, one-time period model) is that demand for long-term care insurance appears to be affected by markets for acute care and rehabilitation, by risk perceptions, and by information and misinformation about what Medicaid and Medicare cover.

There are three grants on the integration of comparative effectiveness research into care delivery. Bhattacharya (1R21AG041112-01) examines how provider groupings affect physician adoption of evidence-based, cost-saving clinical practices. For example, the conventional wisdom is that small physician practices, which account for the majority of patient-physician contacts, are slow to adopt new technology, especially if it requires initial investments of physical capital or learning, compared with salaried physicians working for large health plans. However, the empirical patterns are not so simple, and in any case, the environment is changing rapidly. Less formal networks (such as membership in Individual Practice Association IPA panels or participation in referral networks) may matter as much as formal organizational structure. The findings of this project could prove central to future efforts to encourage evidence-based, efficient patterns of care. Focusing on the consumer perspective, Wong (1R21NRO13584-01) examines alternate ways to encourage diabetic patients to achieve lower cholesterol levels by taking statin drugs - testing the provision of personalized risk and benefit information, cost incentives, and both together. Inclusion of both process measures (did they take their meds?) and outcome measures (did they keep their cholesterol under control) is innovative in this field and results could improve the quality of care for persons with diabetes-a large and high-risk set of patients.

The Health Economics Common Fund program supports research in other areas of health economics as well. For example, Subramanian (1R21CA165093-01) plans to estimate the impact of personalized medicine on the cost-effectiveness of preventive measures against cancer, heart disease and diabetes using a simulation model of individual behaviors and interactions, and assess their collective impact.

Swaminathan (1R21AG042302-01) is analyzing the impact of preventive health care measures introduced as part of the Medicare Prescription Drugs, Improvement, and Modernization Act (MMA) in 2003. He will estimate the effects of Medicare providing free preventive screening for diabetes and cardiovascular disease on subsequent health care costs, utilization, and health outcomes. The findings will improve our understanding of the effect of health insurance coverage for preventive care services.

Muennig (1R21HD071561-01) is testing ways in which informing patients about the value of screening and tests can reduce inappropriate preventive testing (and increase appropriate testing). They will develop an innovative education tool to inform patients regarding appropriate clinical practices for their age, gender, and general risk factors for disease. The project will also provide guidance on how physicians and patients can communicate better about tests to prevent misunderstandings.

Dr. COLLINS. The young researcher, your chance of getting funded today when you send in your grant to NIH is about 1 in 6, the lowest in history. And 10 years ago it was 1 in 3. And you can imagine what that does to a young investigator's circumstances.

In terms of the age at getting your first grant, it has been constant over the past several years at age 42, which we believe is much older than is healthy for the biomedical research enterprise, and we have a number of new programs that are trying to do something about that.

In terms of your question about a cut, I assume you are referring to the sequesters.

IMPACT OF SEQUESTRATION

Ms. DELAURO. That is right.

Dr. COLLINS. If, in fact, the sequesters were to kick in on January 2nd, 2013, that would result, according to the CBO, in a loss of about 7.8 percent of the NIH budget, $2.5 billion. As a result of that, 2,300 grants that we would have planned to give in Fiscal Year '13 would not be able to be awarded. It would be devastating.

INTERNATIONAL INVESTMENT

Ms. DELAURO. So, your buying power would continue to decrease between 18 and 20 percent. The research, if it is not done here is done elsewhere. What is happening internationally? Are they eating our lunch?

Dr. COLLINS. It is interesting if you look across the board. China just announced a 26 percent boost in one year for their support of basic research. India has been in double digit increases for several years. European, despite their difficulties, plan to increase research spending by 40 percent over the next seven years, and even Vladimir Putin last week announced the intention to increase support for Russian basic research by 65 percent.

Ms. DELAURO. We ought to double the amount of money so that we continue on that trajectory of providing the NIH with the resources that it needs in order to be able to look at new efforts as well as to continue the research and other efforts which are important to the well-being of this Nation both physically and economically.

Thank you, Mr. Chairman.

Mr. REHBERG. Thank you. Mr. Alexander.

Mr. ALEXANDER. Do I get a star if I do not ask——

Mr. REHBERG. Absolutely. [Laughter.]

Mr. REHBERG. I will give you a cupcake, but somebody quit bringing those. [Laughter.]

Mr. REHBERG. All right. Ms. Roybal-Allard.

NIMHD INFRASTRUCTURE

Ms. ROYBAL-ALLARD. Dr. Collins, the National Center on Minority Health and Health Disparities has been elevated to a national institute, which expanded its responsibilities and it has given it a more defined role in the NIH research agenda.

The Institute has also assumed additional responsibilities with the transfer of the research centers and minority institutions pro-

gram. Yet despite this expanded authority and the fact that the law provides for administrative support, the NIMHD continues to be understaffed and underfunded.

How do you expect that the Institute on Minority Health and Health Disparities will meet its core mission, administer the RCMI program, and fulfill the Institute's other expanded responsibilities without the adequate funding it needs and staff?

Dr. COLLINS. Thank you, Congresswoman, and you have been an eloquent and consistent supporter of health disparities research at NIH, which is a personal priority for myself and many of us who lead that enterprise.

The National Institute—now it is an institute—for Minority Health and Health Disparities has, in fact, in the course of the last year expanded its efforts by the arrival of the RCMI program, which is, I think, a wonderful place for that important part of what we are doing in terms of minority institution research to be placed.

We have also worked with Dr. Ruffin, the director of the Institute, to deal with the concerns about shortages of staff, and have identified ways to assist with that by the addition of quite a number of additional staff positions to NIMHD, even above the ones that were coming through the RCMI program migrating into that Institute.

And we are supporting strongly, the formation of an intramural program in NIMHD to provide them with additional health research capabilities to undergird all of their efforts in health disparities.

It is important, though, also to point out that while NIMHD is the hub of this activity at NIH, that all of the institutes have engagement in health disparities. The total spending in health disparity research stands right now at about $2.7 billion this year.

PANCREATIC CANCER GRANT FUNDING

Ms. ROYBAL-ALLARD. I would like to go back to the pancreatic research issue. It is my understanding that in the Fiscal Year '2011 plan, that 17 newly competing grant proposals and 59 grant renewals focusing exclusively on pancreatic cancer were funded after falling within what you call the zone of uncertainty. I would like to know how do we figure comparative grants for other cancer types in the zone of uncertainty, and what is the difference in overall funding levels? And also, what criteria are used to determine whether or not a proposal in the zone of uncertainty is being funded?

Dr. COLLINS. So, Congresswoman, all of the NIH institutes have a two-level basis of doing decision making about grant funding. There is the initial study section which reviews the proposals, assigns a priority score, and then there is a second level, an advisory council that then looks at program relevance and balance, and tries to make sure we are spending every dollar in the best way. That is where this second level of the zone of uncertainty kicks in.

In terms of the specifics about pancreatic cancer, I would need to ask my colleague, Dr. Varmus, to answer that for the record because I do not know the specific details of how that compares with what has happened with other cancer applications.

Mr. REHBERG. This would be an appropriate time to say that the opportunity exists for the subcommittee members to ask additional questions in written form and have them——

Ms. ROYBAL-ALLARD. If you would submit that information for the record——

Mr. REHBERG. And have that submitted, correct.

Dr. COLLINS. Happy to do that.

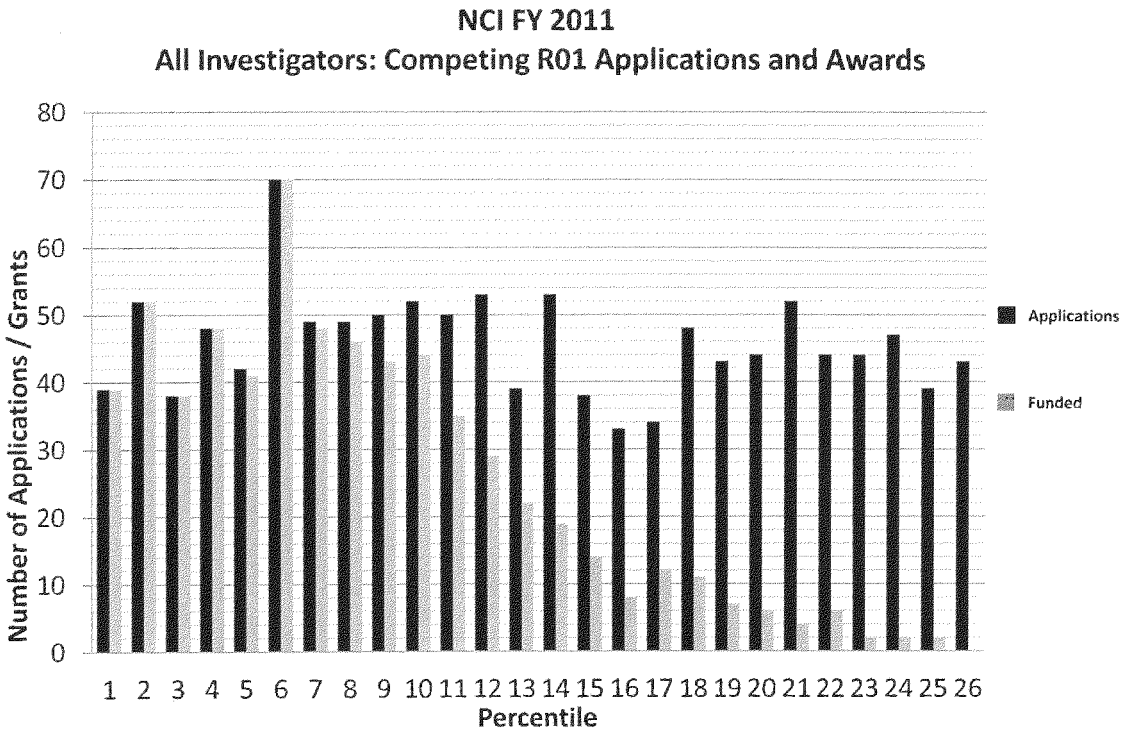
[The information follows:]

House L-HHS-E Appropriations Subcommittee Hearing
The National Institutes of Health (NIH) Pancreatic Cancer Research
April 06, 2012

NCI has been paying special attention to grants that might in the past have been unfunded because they fell below what used to be considered a "payline," a percentile score derived from the results of peer review. Beginning in Fiscal Year (FY) 2011, NCI scientific program leaders have been performing additional evaluations of grant applications to ensure a balanced grant portfolio and to recognize the value of research proposals that are highly original or address important scientific priorities, such as research on pancreatic cancer, even though they might not have received percentile scores that fall within a pre-determined payline. With the new process, applications that score exceptionally well, falling within the top 7th percentile, almost always received funding. Applications that score well, but outside of the 7th percentile, are placed in a "zone of uncertainty" and are further evaluated by the NCI's scientific program staff and leadership before a decision is made about recommending them for funding.

Of the applications that were focused exclusively on pancreatic cancer and were funded in FY 2011, more than a third were selected as a result of this programmatic review, rather than on the basis of receiving exceptionally high scores. While this number is similar to those for grants focused on other cancer types, it is not possible to make simple comparisons because of several complicating factors. First, the numbers of grant applications in most categories for one year are relatively small. More importantly, several factors, including originality, potential for reward, and scientific rigor, in addition to cancer type, are taken into consideration. Furthermore, the existing classification scheme does not adequately reflect the potential importance of many grant proposals to the problems posed by pancreatic cancer. For instance, studies that address genetic, molecular, and biological features of various kinds of cancers are often directly applicable to pancreatic cancer. Finally, this analysis of research project grants does not include several other approaches that the NCI is taking towards pancreatic cancer, including clinical trials (through the Cooperative Clinical Trials Groups), genetic studies (through The Cancer Genome Atlas project), and support through the NCI-designated cancer centers program.

A full list of FY 2011 research funding by cancer type is available on the NCI's website at: http://fundedresearch.cancer.gov/search/funded?action=full&fy=PUB2011&type=site. The numbers of applications receiving percentile scores better than 25% and the numbers with each score that were funded are shown in the attached graph.



Excludes applications that did not receive a percentile score. Includes all applicants (Experienced, New and Early Stage). When an amended application is considered in the same fiscal year as the original, only the one with the better score is counted.

Mr. REHBERG. Dr. Simpson.

Mr. SIMPSON. Well, for the benefit of my chairman, the reason we study economics and the reason we have economists is to make astrology look respectable. [Laughter.]

DENTAL RESEARCH

I would be doing less than my job if I did not ask a dental question. On March 6th, the New York Times ran a feature story about the rise in the number of preschoolers with cavities, citing that in some cases, the decay is severe enough to require surgery under anesthesia. What is the NIH research doing about cavities in this early childhood group? And also, where are with saliva research?

Dr. COLLINS. Thank you for the question. And my good colleague, Dr. Tabak, who is now my principle deputy, indicated to me that you might potentially ask dental questions, Doctor.

So, in terms of early childhood caries, yes, there are serious difficulties encountered, particularly in minority communities, and it may relate to a combination of a limited access to fluoride, but also to dietary practices that are resulting in sometimes very severe consequences.

The National Institute of Dental and Craniofacial Research (NIDCR) is certainly very interested in this and has a research program to try to uncover the causes both in terms of biological and behavioral, and is conducting research through centers in dental research that are focused particularly on particular populations that are vulnerable to this problem. So, this is a health disparity, just like what we were talking about a moment ago.

In terms of saliva as a window into the body, maybe not the soul, but the body, these days if you are going to have a genome test, what you usually do is spit in a tube, so you know there must be DNA in there. And there is a lot of other stuff, too. Saliva does sort of become a filtrate of what is going on inside the body, and so it is a way in which experimental protocol, looking to see early evidence of a heart attack from saliva. And certainly this is also a place where with some new technology, one can develop tools for looking at possible signs of oral cancer. The NIDCR has investments in research in both of those areas, and they are going quite well.

Mr. SIMPSON. Thank you, and thanks for all you do out there.

Dr. COLLINS. Thank you.

Mr. REHBERG. Ms. Lummis.

DRUG REPURPOSING

Ms. LUMMIS. Well, thank you, Mr. Chairman.

I want you to know I really have a lot of regard for what you are doing. I want to echo what Dr. Simpson said. This is an area where I believe the Federal government has a role because there are so many diseases that are suffered by people that will never have a cure because unless the Federal government gets involved in research because the economics just is not there.

So, I want to give you a chance to put NCATS' best foot forward. One of the areas where it looks to me like there may be duplication with what the private sector can already do is in the area of a drug

repurposing program. So, I want you to explain to me how that might operate.

It seems to me if there is already a drug out there that has one application, that the entity that would be the most interested in seeing if there are any other efficacious applications would be the drug company that holds the patent. So, why would you want to spend time and dollars duplicating what the private sector might do with its own patents rather than exploring areas where there has been almost no research into a disease solution?

Dr. COLLINS. Again, let us talk about rare diseases. I think that is a big part of the answer because drug companies because of their commercial circumstance and their stockholders' expectations are not likely to see it as commercially viable to try to develop a new treatment for a disease that only affects a few thousand people.

But maybe in the freezer is the drug developed for some other purpose which turned out not be successful for that purpose that now with many new discoveries coming forward with rare diseases might be just the thing.

NIH's goal here is not to step in here and pry things loose from any company that does not want to offer it. But we hear companies saying, we are really interested in this, and in having NIH serve as an honest broker, a sort of clearinghouse, for compounds to find new uses, and to enlarge, therefore, the universe of opportunities beyond what a company might themselves see as a practical way of repurposing.

Ms. LUMMIS. So, you would only use the repurposing program for a currently existing drug if the patent holder or intellectual property holder asked you to?

Dr. COLLINS. Exactly. They would have to make the compound available and say we are interested in having this one looked at by other investigators who might have a new idea about how to use it.

NCATS PRIORITIES

Ms. LUMMIS. Okay. And with regards to other components of NCATS, can you give examples of specific diseases that you see as being priorities for your initial foray?

Dr. COLLINS. Again, NCATS' focus is really on finding those bottlenecks in the pipeline, and so it is more of a generic strategy. There is a component of NCATS called Trend. Dr. Insel might mention a couple of the program's specific diseases, but they are sort of proofs of principles to show that this de-risking process can work.

Mr. REHBERG. Very quickly, please.

Dr. INSEL. Right. So, there are 14 projects across 14 diseases, many of which you have never heard of because they are very rare. But they are not chosen because of the disease. They are chosen, as Dr. Collins just said, because they provide a prototype for us to reengineer. This is what NCATS is all about. It is looking at the pipeline, figuring new ways to develop compounds, new ways to develop diagnostics.

Ms. LUMMIS. Thank you, Mr. Chairman.

Mr. REHBERG. Thank you. This segment will conclude. As I suggested, the record will be left open for additional questions if you would respond in a timely fashion.

Mr. REHBERG. And we will invite the next panel up, please. Thank you, gentleman.

Dr. COLLINS. Thank you.

TUESDAY, MARCH 20, 2012.

BUDGET HEARING FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES—NIH

WITNESSES

SCOTT KOENIG, M.D., PH.D., PRESIDENT AND CEO, MACROGENICS, ON BEHALF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION

TODD SHERER, PH.D., CHIEF EXECUTIVE OFFICER, THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH, NEW YORK, NEW YORK

P. ROY VAGELOS, M.D., CHAIRMAN OF REGENERON PHARMACEUTICALS, INC., RETIRED CHIEF EXECUTIVE OFFICER AND PRESIDENT OF MERCK CO., INC., AND POLICY ADVISOR TO THE PUBLIC AFFAIRS ADVISORY COMMITTEE, AMERICAN SOCIETY FOR BIOCHEMICAL AND MOLECULAR BIOLOGY

Mr. REHBERG. All right. We will begin. Dr. Koenig, why don't you start, if you would, please.

Dr. KOENIG. Good morning, Chairman Rehberg, Ranking Member DeLauro, members of the committee, and ladies and gentlemen. I am Scott Koenig, president and CEO of MacroGenics and chairman of the board of AGTC.

I worked at the NIH and the biotech industry for the past 28 years. I have been involved in the development of biological products. I am appearing today on behalf of the Biotechnology Industry Organization.

It is my privilege to testify before the subcommittee. I have submitted testimony discussing the importance of NIH funding in order to maintain our global leadership position in biomedical innovation to ensure a robust biotechnology industry in the United States, and to deliver the next generation of medicines to patients.

My comments today will focus on the National Center for Advancing Translational Sciences, or NCATS.

BIO is supportive of the NCATS' stated mission to catalyze the generation of innovative methods and technologies that enhance development, testing, and implementation of diagnostics and therapeutics. It is important for NCATS to establish a very focused set of priorities for each of its initiatives that individually and collectively will serve to improve research and development processes.

BIO also agrees with the language in the 2012 appropriations report and statements made by the NIH that research undertaken by NCATS should not be duplicative of the research and development done by industry.

The primary metric for determining the success of NCATS is whether the initiatives will yield significant reductions in time and expenses in the development of new therapeutics, expanded terrain

of novel targets and pathways, and ultimately improve the delivery by drug developers of the next generation of medicines to patients.

In order for NCATS to achieve its goals, they must develop substantive partnerships and collaborations with industry regulators, principle investigators, life science investors, and patient organizations. It is crucial that research priorities are developed with input for those who are working in the trenches and are most knowledgeable about where scientific barriers lie and where adjustable inefficiencies exist.

Among the inaugural programs that have been highlighted by NCATS is NIH-DARPA-FDA collaboration to identify methods and tools that will enable drug developers to better predict toxicology in humans, and early in the drug development process, the so-called tissue chip that Dr. Insel showed you this morning.

Such an initiative should be universally endorsed. It is a winning proposition if they are successful. Likewise, efforts to identify and validate drug targets more efficiently would help to maintain a robust pipeline and potential breakthrough treatments.

The question that was asked at the end of the last session, the program to repurpose and rescue drugs, is a perfect example where collaboration between NCATS and industry is vital. Industrial partners will be required to develop, manufacture, and market these drugs, and we encourage NCATS to identify partners early with industry so they may ensure that they are addressing issues, such as intellectual property, quality assurance, and the design and conduct of clinical trials.

NCATS' efforts should not be redundant with translational work being done at other centers at the NIH, but we believe that NCATS can serve as a point of contact and convener for meetings as a way for public/private partnerships, industry, and other stakeholders to reach out to NIH with potential new research collaborations and maintain a dialogue in a systematic and transparent manner. The vast majority of NCATS' budget is dedicated to the CTSAs that you heard about earlier.

We encourage the engagement of CTAs and clinical investigations that help to validate bio markers, identify the impact of specific genes or epigenetic factors that would predict clinical efficacy or safety signals within certain populations or within particular classes of drugs, and establish principles to conduct in clinical studies with innovative designs, particularly those that demonstrate synergies among classes of molecules that would lead to better therapeutic options for patients.

NCATS has a real opportunity to take a leadership role in improving the science of drug development. The success of these discoveries will only be realized if they are adopted in advance by industry, and it is imperative that NCATS work closely with the FDA to foster the development and adoption of these new tools and practices.

Finally, I would like to briefly discuss the Cures Acceleration Network Program. BIO has long supported this initiative. We think this provides a unique opportunity for industry and other stakeholders to collaborate with NIH and FDA on innovative drugs to treat diseases of critical importance to public health, and to fund programs, such as treatments for ultra-rare diseases that are gen-

erally not supported by the private sector. BIO is interested in continuing to work with NIH as this new program evolves.

So, in conclusion, Mr. Chairman, we believe that there is a real opportunity to systematically identify key scientific areas of research, such as predictive toxicology, tools and methodologies to accelerate target identification and validation, and to improve clinical trial efficiency so that ultimately it would serve to enhance the development of new drugs as a whole. And I thank you for the opportunity to testify today, and we look forward to continuing to work with Congress and the NIH as this new center evolves.

Mr. REHBERG. Thank you, Dr. Koenig.

And welcome, Dr. Sherer.

Mr. SHERER. Thank you, Chairman Rehberg, and Ranking Member DeLauro for inviting me to testify today on the National Center for Advancing Translational Sciences.

I am the CEO of the Michael J. Fox Foundation for Parkinson's Research. Our foundation has a single mission: fund research that will speed the cure for the 1 million Americans suffering from Parkinson's disease, a debilitating neurodegenerative disease without adequate treatment.

Since our launch in 2000, our foundation has developed more than 100 Parkinson's disease therapeutic targets, pushing dozens of these closer to the clinic for relevance in patient's lives. Our urgent goal is to prioritize our limited resources within the complicated drug development process for the maximum impact for patients' lives. To produce one drug for Parkinson's disease can take over 15 years and up to a billion dollars of investment. I frequently have used the alphabet as an analogy to highlight the complexities that result in the high costs and long lead times.

In the first part of the alphabet, say, letters A through F, there were aha moments where an academic scientist looks at some aspect of biology and asks, can this be important? This discovery science is the backbone of all drug development that occurs. Our foundation's impact is possible because we strategically build off the Federal government's ongoing investment in discovery science through the NIH. But when it comes to developing cures, questions at this level are the first step of a thousand mile journey.

The next chunk of the alphabet, say, letters G to P, is translational research. This is the applied work where scientists hone in discoveries from the A to F phase, looking for disease specific effects. Translational research asks the questions that must be answered before we can take the critical leap to test the potential therapy in humans. The problem is this is far easier said than done.

This phase has been dubbed the valley of death because of the chronic funding and expertise gap that is crying out to be addressed like an institute, like NCATS. For now and fortunately, this is where potential treatment breakthroughs go to die.

The very few novel approaches that do make it out of this middle phase still have to navigate the final part of the alphabet—call it Q to Z—which is largely handled by the private sector. In this final stage, potential new drugs initiate clinical testing and ultimately will seek regulatory approval. But funding capital here is becoming more and more risk adverse.

NCATS can play a vital role in making drug development more efficient and effective for generations of Americans, and I would like to share a few learnings from the time and work at our foundation that may be helpful in thinking about NCATS.

First, the research enterprise is made up of multiple well-intentioned, but differently incentivized stakeholders. For an academic researcher, success means publication and promotion. For industry, it is patentable assets. But for patients, it is critically needed new treatments. No one is orchestrating the efforts of all these different players. As Michael J. Fox has said, there is no department of cures.

Progress requires a conscious decision to elevate translational science, including an appreciation for what it is, why it is vital, and what strategies can help foster success. Creating a culture of translation within the NIH is bigger than any single disease and bigger than the work of our foundation.

Second, our foundation realized early on that to drive Parkinson's breakthroughs, we need to make investments in applied biology to transform basic discoveries into practical treatments. This does not happen on its own. The tough truth is that our system largely fails us right where it should be working the hardest. A successful NCATS would make a tangible difference by strategically building the right pools of expertise where they are needed most, at the Q to P translational phase by supporting creative, higher risk approaches to drug development and leveraging collaborations with patient organizations, academia, and industry. This will ultimately move projects faster through the drug development pipeline for the benefit of all Americans.

Third, at the core of our foundation's daily work lies a single purpose: allocating resources wisely with Parkinson's patients benefit in mind. NCATS can seize the opportunity to represent patient relevant investment on a larger scale, impacting the lives of countless Americans. This means not only orchestrating work within the translational stage, but also stepping in to champion projects that would otherwise languish because they hold no incentive for the private sector. It means repositioning existing drugs that hold promise for untreated disease, and importantly investing in precompetitive research tools that can move the entire field forward faster.

Fourth, we have heard from those who believe that the private sector alone bears the responsibility for bringing new treatments to market. In our experience, this just does not work. The challenge is not getting the private sector to pick up a promising idea that has made it all the way to letter Q in the clinic. The challenge is getting it that far in the first place, particularly when economic realities and research challenges are making it harder, not easier, for companies to invest in high risk science.

The drug development system impacts generations of Americans. I hope the core values for translation I have shared today, aligning stakeholders to enable better handoffs from one stage of research to the next, adequately investing in applied science, maintaining a patient oriented perspective, and reducing risk in order to position projects for private sector investment will be helpful in shaping the future of NCATS. It is one of our greatest hopes that we will have

the opportunity to work with NIH and NCATS leadership to usher in this new institute.

I would like to thank the committee for the opportunity to be here today. As Michael J. Fox has said, the answers we want are not going to fall out of the sky. We have to have ladders and climb up and get them.

Thank you, and I am happy to take any questions.

Mr. REHBERG. Thank you. Dr. Vagelos, welcome. Good to have you.

Dr. VAGELOS. Chairman Rehberg, Ranking Member DeLauro, I am happy to be here. You have seen my statement, so I am not going to read it.

Mr. REHBERG. Thank you.

Dr. VAGELOS. Yes. I would like to just make a couple of comments that might be helpful.

The reason I outlined my background is that I have had, because of a long history, experience in clinical work, having taken care of heart patients. I have done basic research. I was 10 years leading the Merck Research Laboratories, and then for 9 years I led the company. I had to retire at age 65 because of board policy, and then became chairman of two biotech companies. So, I have a broad experience across the field.

My message to you is one, and that is we have heard it two times. Dr. Insel and Dr. Collins both referred to the lack of knowledge to do various things. Pancreatic cancer for one. I have forgotten what Dr. Collins landed on.

The history of the success in our country in the biomedical sphere is based on the basic research that is funded almost entirely by NIH and in public funding. The translational or applied research typically is done in industry and done well. We have a wonderful history.

I have outlined the history of the development of the statins, which the first one introduced by Endo in Japan, that is a compound was discovered, was found to have problems in humans, and that is when the Merck competitive spirit took over and produced the first statin in the world. And then that was lovastatin, Mevacor. And then when the doctors who believed in the cholesterol hypothesis used it, others did not because they said, lowering cholesterol, what good is that? Merck brought along the second statin, which was simvastatin, Zocor, and did a huge outcome study which demonstrated over a 5-and-a-half-year period that one could reduce mortality by 30 percent and decrease that from heart attacks by 43 percent. That was introduced and started the statin revolution of cardiovascular disease treatment.

So, we have a history at Merck. We introduced the first vaccine against Hepatitis B, a virus that causes liver cancer. And, of course, Merck introduced a second vaccine that prevents cancer, and that is a vaccine that gets human papilloma virus that prevents cervical cancer. So, the company has been involved in first drugs for glaucoma, osteoporosis. It goes on and on. And much of that started while I was at Merck.

And so, my issue is that we have an enormous need for more basic research. We have succeeded up until now. We do not want to change that paradigm. Is the paradigm broken? Is basic research

evolving that is now picked up quickly? Thank God. Now, I do not have to shout. [Laughter.]

And my answer is no. When basic research, which we desperately need in all disease areas, becomes available, companies move fast. I will give you two examples that are in racing in the clinic today. One is we know very definitely that LDL-cholesterol, lowering that causes a reduction in coronary heart disease. And there is a new mechanism that has been identified in the last four or five years that targets a new enzyme other than what the statins do. And that is PCSK9. And if you can block that as found in people who are normal, walking around, and never get coronary heart disease, but have extremely low density for protein cholesterol, if you can do that, they are predicting that one could take another step in prevention of heart attacks.

There are probably at least four companies racing to do that. They have gone through phase two, and that has all happened in the last five years at one of those companies, which apparently is in the lead, is Regeneron, the company I chair, by the way.

Now, the other one is SMA, skeletal muscular atrophy. This is a terrible hereditary disease that affects thousands of children in this country and the world. And the defect was identified very recently, and there are three companies racing, one of them already in the clinic, two others going into the clinic.

So, my message is we lack basic research. Some of the things NCATS proposes to do are certainly worthy. There are some of them that I would say are not worthy of support. And when I know that only 17 percent of people who finish their work and are requesting their first grant, only 17 percent are being funded, that is a direction for disaster in this country competitively.

Mr. REHBERG. Great. Thank you very much.

You have done it all, which is interesting, and I appreciate the opportunity then to ask you, you know, there are some of us that are specialists and some of us that are all arounds. But it sounds like you have been involved in just about every segment.

So, I would like to ask you what or who, if you were the NIH god and became the director tomorrow, how would you implement NCATS? What would you do to change the relationship between industry and the government, the Federal government? Obviously I think your focus was on basic research, which is fine. But could you expand a little on how you would design NCATS and change functions within the NIH to better provide the efficiencies that are necessary based upon the dollars we spent, but, more importantly, on providing the service to the public that we intend?

Dr. VAGELOS. Chairman Rehberg, I probably would not have started NCATS. In the priority of things, I think that while NCATS, the things that they are proposing to do can be helpful, they are not the limiting issues in development of new drugs. They just are not.

Just look at relative budgets. The budget of the NIH is about $30 billion. NCATS is about $575 million. The budget of industry, pharmaceutical biotech industry, I do not know what it is. I think it is about $50 billion. Now, does anyone in the total audience believe that there is something that NCATS is going to do that the industry thinks is critical and that they are not doing? I think that is

incredible to think that. If you believe that, then you believe in faeries.

Mr. REHBERG. Okay. Dr. Koenig. Maybe you have had the experience. I do not know if you have been involved in clinical studies.

Dr. KOENIG. I absolutely have been involved in clinical studies. I have worked at two biotechnology companies for 22 years, and have been involved in clinical research, actually improving the implementation of these studies. And it is sort of a vast field. I mean, we have been involved in immunology research that transcends autoimmunity, cancer, infectious diseases. So, we have a widespread view of the applications of various drugs and what they can do.

With all due respect to Dr. Vagelos, I think that there is a unique opportunity that NCATS has sort of pointed out. We definitely agree that when a particular target has been identified, the drug industry, which includes biotech industry, is best suited to ultimately develop that drug and do it well. But what has proposed are sort of new initiatives to fill the gaps, and the things that I have sort of highlighted today in terms of predictive toxicology, this is not an initiative that drug companies would be working on to move advances in a particular drug for a particular indication.

The idea of identifying surrogate markers. Now, one of the biggest troubles in terms of the whole development process is that we do not know what ultimately how a drug will work in every way, shape, or form. And so, if we are able to reduce this in a laboratory test to identify something that will give a response that ultimately years down the line will produce a clinical benefit, we have an ability now to shorten that whole process of drug development and get drugs to patients much earlier.

Again, this is not something that the drug industry spends a lot of time and effort on. So, these are two of many things.

Mr. REHBERG. If I could stop you there just so Dr. Sherer has an opportunity to answer. I have about a minute left on my time.

Mr. SHERER. Yeah. Also I guess I have a different take on this than how it is presented because I know from the work of our foundation, we have about $50 million of research each year, and we feel we are making a significant impact because there are clear areas that the industry does not focus on. And I think things that NCATS can do that would actually make the $50 billion that industry is spending more efficient and have a greater chance of actually leading to more therapies, things like clinical trial efficiencies, how clinical trials are conducted, diagnostic tests.

And then this comment about identifying targets, identifying targets, as I mentioned in my statement, is the first step. And with the technologies that Dr. Collins was talking about, we are identifying thousands of new targets. And there needs to be work done to really prioritize those for the industry because the industry is not going to pick up on all of these targets.

So, I think there is a lot that can be done by NCATS with the budget that they have to make a significant difference.

Mr. REHBERG. Great. Thank you.

Ms. DeLauro.

Ms. DELAURO. Thank you very much, and I want to thank the panel for their testimony. I want to get to Dr. Sherer.

But, Dr. Vagelos, I think you have made the case for NCATS here this morning in that this is not an issue of what industry needs, quite frankly, or the top five illnesses. But it is a question of what patients need and the therapies and the treatments, et cetera. And it is what the rare diseases that are out there need, the orphan diseases that are out there, quite frankly which the top five or big pharma is not undertaking.

And with that, let me move to Dr. Sherer because I want to just probe a little bit more with you what you started to talk about.

I think your presence here today really keeps us focused on the prime effort of medical research, develop better ways to prevent and treat disease and to improve health. The foundation is very focused on not just improving our understanding of Parkinson's disease, but also translating that understanding into things that will actually be available to help patients as quickly as possible.

What can the NIH do to help organizations like yours that are seeking to bridge that gap between advances in basic science and the availability of new treatments for patients? What role would you like to see NCATS play that individual organizations like yourself cannot? And if you have time, what issues related to Parkinson's or neurology would you like to see NCATS take on?

Mr. SHERER. Thank you for the question.

I think this is really an important issue in that every disease can have a champion like the Michael J. Fox Foundation, but there are pretty significant challenges about developing drugs for neurology that are beyond the scope of activity that an individual foundation can have. And they are not being picked up and dealt with right now by the pharmaceutical industry, who needs also the help that NIH can provide or NCATS, for the benefit of patients. And these include some of the issues that were talked around safety and toxicology, some of the issues around the fact that we work on Parkinson's.

There are a lot of age-related neurodegenerative diseases that have commonalities—Alzheimer's, Parkinson's, Huntington's disease, some common challenges that NCATS can address related, again, to safety, toxicology, clinical trial efficiencies, diagnosis, tracking of the disease. These are really critical issues that can be addressed by an entity like NCATS that would benefit not just people with Parkinson's, but people with all diseases.

Ms. DELAURO. Okay. Let me just ask Dr. Koenig, do you want to comment on any of that? This was specific to Parkinson's, but go ahead.

Dr. KOENIG. Not specific about Parkinson's, but, again, actually if I think of what NIH can do with organizations like patient organizations and working with companies, I actually think back to my days at NIH and the evolution of how industry has interfaced with NIH. And I think over the years it has become closer and closer because we understand that there are gaps that industry can fill, and that NIH needs to provide. And this actually is reflected even in the granting process.

What I have seen from the history of grants is that many of these grants now are actually seeking partnerships between the basic researcher and companies to work on new initiatives. And I actually implore that in this NCATS initiative that they actually

spend a lot when they go out working with the new grants initiatives, that they include that as a preferred way of conducting research because actually as a team we can work together ultimately to get a better pathway and assure the development of new drugs.

Ms. DELAURO. There is a short time, Dr. Vagelos, and we are going to come back. But you——

Dr. VAGELOS. I just wanted to say one thing to speak to the rare diseases and diseases that are not going to have profits, orphan diseases. A small company, Regeneron, worked on CAPS, C-A-P-S, which is an acronym for a disease that affects a couple hundred people in this country, and developed a drug and put it on the market, really making very little money at all. A tiny company whereas Merck had a drug for animals, killing of parasites, called Ivermectin. And we discovered that it worked in parasitic diseases characterized as river blindness in Sub-Saharan Africa. That was going to make no money at all. We knew that when we started.

We carried out an eight-year development program to show that it was safe and effective, and then started giving it away in 1987 to all people in Sub-Saharan Africa and other parts of the world, and are treating at this time. Merck is now treating, let me see, 95 million patients a year free.

Ms. DELAURO. I would just say, let me just finish this, Mr. Chairman.

Mr. REHBERG. You may.

Ms. DELAURO. My point was not about the money. My point was that the decision, as you put it, you know, it is what industry decides we should move forward on. I just do not happen to believe that that is the way that we ought to make a determination of what efforts, and what research, and what science we move into. That was my only point. It had nothing to do with money.

Mr. REHBERG. Mr. Alexander.

Mr. ALEXANDER. Thank you, Mr. Chairman.

The question is for whoever wants to answer it. But what can we do to coordinate efforts between the NIH and NCATS to improve the way the pharmaceutical companies can move more quickly from discoveries to treatments?

Dr. KOENIG. As I described in my testimony today and in testimony, I think that NCATS has a great opportunity now to sort of be the convener, the go to part of NIH that can be bridging the relationships between patient organizations, industry, and others where they can hold meetings, where they are very transparent on what their initiatives will be. And it gives an opportunity now for industry and NIH to get together so that industry can propose new research collaborations.

I think that ultimately the aha moments that were described earlier occur when we put together the drug developers, the patients, and scientists who are working on basic research in a room. And it happens typically at meetings working on particular diseases.

But this is an opportunity now with a focus on, again, the things we talked about, predictive toxicology, and looking at surrogate biomarkers, how these teams can work together.

So, again, forming a sort of a consortium between the various members here could, I think, help to accelerate the development of new drugs.

Mr. SHERER. I would just echo those comments, and I think the centralization of this information and expertise will be very critical. It does not just look necessarily at one disease, but can look at the application broadly for human health. Bringing the stakeholders together would be important.

Dr. VAGELOS. I do not think there will be any acceleration at all by the NCATS of things that are recognized as important by people in the community, by people in industry, and by people in academia because industry is so focused to get something done when the science is available, and the science can impact a disease. Whether it be a large disease or a small disease, they really are critical, and they have the passion for drug and vaccine development.

And the amount of money that is funneled at that is huge, and, therefore, I think that the money that is going to NCATS, if it could support those other than the 17 percent of young Ph.D.s and M.D.s who are getting their first grant so that we support more of those, we would be doing a lot more good for getting important new drugs on the market.

Mr. SHERER. I would actually just like to come back to what Ranking Member DeLauro said because we have seen even in our space, in Parkinson's, the changing landscape in the pharmaceutical industry, we have seen many of them merge and combine in the last couple of years. And I do not share the view that in all cases the decisions are solely made on a scientific or patient focused basis.

So, I think obviously our foundation strategy is to de-risk projects and get industry more involved in Parkinson's, and work with them as part of the collaborative network. But I think it does need to be a collaborative network of patients, the government, and industry, and not just solely relying on one entity alone to sort of help us all in the end.

So, just it is my view, but I think that is kind of the evolving framework of the industry, and we should understand that and now figure out our goal is to develop treatments for patients, and let us try everything we can and not just the same old thing that has been tried in the past.

Mr. REHBERG. Ms. Roybal-Allard.

Ms. ROYBAL-ALLARD. As you know, moving therapies further down the development pipeline is one of the focuses of the newly-formed National Center for Advancing Translational Science through its Therapeutics and Rare and Neglected Diseases Program. Yet in your testimony you encourage NCATS to otherwise focus primarily on pre-clinical and early clinical studies.

What is your view of the proper boundaries between the work of NCATS and that of the private sector, and what is best for government, and what is best for industry? And how do you recommend that NCATS directly contribute to both early and more advanced translational research without being duplicative of efforts already under way by industry, medical research institutions, or other NIH grantees?

Dr. KOENIG. Thank you very much, Congresswoman, for the question.

I did, in fact, emphasize in my written testimony that the focus of the NCATS should be on the early clinical assessment of these opportunities, again, in the context of things which I talked about, treatments for rare diseases, which could go a little further into phase two development, because, again, the concern that the private sector does not support this as well as it should.

But I think there is an opportunity for NCATS to actually give a focus on smaller populations where they can get insights on how a drug may be developed, identifying these new surrogate markers that could be worked on.

I agree with Dr. Vagelos here that once industry has a drug that has a proven safety record, that they do the latest stage development, phase two developments, the design of those studies much better than what would be done by NCATS and the NIH. And I think that it is important that when NCATS moves into phase two development, they reach out to industry for their advice because I have seen many cases, for instance, where a principle investigator wants to do a phase two study with a compound, and then will spend millions and millions of dollars doing that study, and it is done under circumstances that ultimately when that data comes out cannot be used for the registration of that drug down the line with the FDA.

And so, I think there are lost moments there when in the rush and the design of these later stage studies by the NIH investigators supported by the NIH, they are not looking at sort of the full long-term view of the value of that clinical trial and later stage drugs for the ultimate registration of the product. So, that is where I think industry definitely needs to have a hand, work if it actually gets to phase two, with the NIH investigators. But ultimately I think it is industry that needs to move forward in phase two and three development.

Ms. ROYBAL-ALLARD. And, Dr. Sherer, with regards to your foundation, can you elaborate a little bit on what progress the foundation has made on Parkinson's therapies, and what contributions has NIH sponsored research made to that progress?

Mr. SHERER. Yes. So, one of the areas that we have focused a lot on is what we call target validation. This is really that first stage of translation where you are taking discoveries out of NIH funded labs that maybe have identified a new target that may have potential as a treatment for Parkinson's, and now you are doing some of the more specific direct tests for Parkinson's.

And there are a number of specific examples where we then had funded some work in the pre-clinical testing, moved that target now to early clinical testing, and we now have phase two trials being conducted by the pharmaceutical industry on those targets for Parkinson's.

So, it really was a targeted focus on that gap I talked about, the middle of the alphabet. NIH funded research had provided very clear promising new discoveries, and then we came in with our focus on Parkinson's, how to accelerate this as quickly to the clinic for patients. We had pharmaceutical companies working with us to

prioritize the studies, and now they have molecules being tested in the clinic.

So, our foundation has already been around for 10 years. I have talked about the timeline, so we are hopeful that some of these trials will result in new therapies, but we know that there are new trials happening because of that work.

Ms. ROYBAL-ALLARD. This may have been somewhat answered in the past, but what role do you believe NIH can and should play in fostering the development of therapies for rare and neglected diseases where there is less incentive for involvement by industry?

Mr. SHERER. So, I think it is a similar role that we have played for Parkinson's that could be looked at more broadly, and really looking at what is coming out of the basic science, what are the most promising avenues, and move those forward from a therapeutic perspective.

But I think even more important if you even wanted to encourage more industry investment in some of these areas, is understanding the clinical testing in those diseases. How will that happen? Make it more efficient. Put the tools in place that could be used in future trials because it is a lot to ask a company to develop the drugs and the tools and all the information. And I think this is where NCATS could really coordinate all of that effort with the patient interest, the pharmaceutical expertise, and the academic knowledge.

Ms. ROYBAL-ALLARD. Thank you.

Mr. REHBERG. Ms. Lummis.

Ms. LUMMIS. Well, thank you, Mr. Chairman.

It was fun to hear that Ivermectin has found a use outside of our uses. You know, I will bet between Mr. Rehberg and I, we have administered tens of thousands of doses of Ivermectin to our livestock. And what a neat thing to find out that there was an application for human use and to alleviate human suffering.

In my job, you know, I seek counsel from the Bible for my soul. I seek counsel from Merck's veterinary manual for my livelihood and my stewardship obligations. [Laughter.]

Mr. REHBERG. Ms. Lummis, for those of us who maybe sometimes accidentally jabbed ourselves, it is also nice to know it is safe. [Laughter.]

Ms. LUMMIS. Exactly. Yeah. I have been vaccinated for red nose, black leg, you name it, as have you. Yeah, Bang's disease.

Let me go on to, I am trying to hone in on where the Federal role ends and begins, and where the private sector role ends and begins, if we can get there.

It is my understanding that NIH uses a more academic model for its clinical trials, and industry may have to repeat clinical trials conducted by the NIH because they do not meet FDA standards. So, my question would be, how do we create some fairly clear lines? And have there been discussions between the private sector industry and NIH about how to set those lines? Yes, sir.

Dr. KOENIG. So, let me comment that the NIH conducts its clinical research with FDA guidance and approval, so they are not below standards, meeting what is appropriate for patient population with regard to safety and oversight for those trials.

However, as I was trying to allude to before is that industry will sometimes include testing, oversight, quality assurance, that NIH does not have the infrastructure to do. And so, ultimately as the point I was making, it is fine for NIH to conduct phase zero and phase one studies and early phase two studies, again, particularly in the case of rare diseases where, again, I think industry could do a better job, but is not incentivized there. But once it gets to that phase, it is very important that we use drug industry standards, biotech industry standards for conducting these trials for oversight because it could be as important as is how that drug is made.

So, in particular, biological molecules, if they are not appropriately characterized in full and they go through this clinical process and get into phase two without the right to oversight on how to manufacture this at scale. If you have to now go back to phase zero and one testing, you have now lost a lot of opportunity and a lot of money that was put into those phase two studies that cannot be used for registration of those drugs.

So, I think, again, as a little blurring of the line, I would say phase zero, phase one, NIH some phase two for certain indications. Work with industry, but once it gets to phase two, particularly two development, three development, et cetera, that should be in the bailiwick of industry.

Ms. LUMMIS. Dr. Vagelos, do you have a comment on that?

Dr. VAGELOS. My comment is that I cannot emphasize enough the need for new knowledge because it was referred to by both Dr. Collins and Dr. Insel to really make important new drugs. And that is what we lack. And that new knowledge is going to come from NIH funded research, young people finishing their post-doctoral training, and getting grants. It boils down to that.

We are shrinking that groups whereas the Chinese are going into it, the Russians are going into it, the people in India are going into it big time.

Ms. LUMMIS. Yep.

Dr. VAGELOS. We have been the leaders of the world up until this time.

Our young people are still coming to the universities to get their degrees, but what they are hearing now is grumbling among their mentors and the professors who are struggling to get their research funded. And this is discouraging. It is discouraging to the young people who are the blood of the future of our competitive position in the world. And we cannot be in this position.

Now, if we are going to be starting other initiatives and not fulfilling that need, I think we are not doing the right thing.

Mr. REHBERG. Thank you. Mrs. Lowey.

Mrs. LOWEY. Thank you very much. And, first of all, Dr. Collins, Dr. Insel, Dr. Fauchi, Dr. Verma, I apologize because of an urgent commitment that I could not be here. But as you know, I am a strong supporter of the National Institutes of Health, and that is why I am so dismayed that the budget request proposes level funding. I understand we are in a difficult fiscal climate, but NIH research saves lives, creates jobs, makes us more competitive.

I think it is imperative that we provide the NIH with a minimum of $32 billion, and then we could solve so many of the other problems.

Secondly, I am sorry I missed your panel, but I am delighted to welcome Regeneron here. Regeneron is in my district, and I know that Regeneron started with four employees; you are up to 1,700 employees in the United States of America. And so, congratulations. I am very thrilled.

Now, with regard to scientists, I remember very clearly at one of the roundtables I had where Regeneron participated, one of the smaller companies, three employees, said they went to China, they met with all the appropriate people, they said, what are you going to do for us. Come back at 4:00—it was about 1:00 I think. I do not remember it exactly. Come back about 4:00, and we can provide 40 scientists to you to work with you in this small company. So, what you are saying, Dr. Vagelos, is absolutely correct, and very frustrating to me.

And I would like to ask you two questions. Number one, you already said something about the NIH. What else could this committee do to support the training of young scientists?

And then I would like you all to respond. I read parts of the book, and I have been in discussions with people who are talking about industry doing "me, too," drugs. And a lot of the energy and the focus can be put on new challenges rather than the "me, too," drugs.

And, thirdly, you talked, Dr. Vagelos, about statin drugs. Now, what should people like us do, choose between diabetes, losing our mind, or a heart attack? [Laughter.]

You can answer in what order you choose.

Dr. VAGELOS. Whatever order. Yeah, thanks, Mrs. Lowey.

Mrs. LOWEY. Because I know we have limited time.

Dr. VAGELOS. It is nice seeing you in person.

First, what can we do about training new people? I think support of graduate programs, both Ph.D. and MDPh.D. programs, and post-doctoral fellows is crucial to keeping the pipeline of exciting young people coming in in both academia, and NIH, and industry. That is crucial.

What we are talking about is a finite amount of money and how you carve it up. I think that is a very important area to continue supporting.

Secondly, "me, too," drugs. "Me, too" drugs are generally when a company starts research on a drug target, they may or may not be the first one on the market. If they are not first, they hope to have a better follow-up drug, and so they continue. But if they finish and they have put now $100 million into it, and they have one that is only as good as what is out there already, the marketing people go ahead and sell it. So, that is sort of a mistake along the way, and I do not support those things on the market, but that is a different thing. Those are failures of the industry frankly.

Thirdly, solution. What was your third aspect? Remind me.

Mrs. LOWEY. No. We have all read the research about statin drugs.

Dr. VAGELOS. Oh, the statins, okay. The statins are probably one—I would look around this room and say, how many people are on a statin? And those of you who are not raising your hand, you are making a mistake because they are incredibly—they have been

studied probably more than any class of drugs that I am aware of. They are taken very broadly. They have enormous benefit.

If there are risks that we still are not sure about because I am not sure if any of these things that have been raised, like fuzzy, loss of memory, diabetes, which have not been found in any of, I would say by now, hundreds of trials, they must be extremely rare, and the benefit is so enormous that I have continued taking statin.

Mr. REHBERG. Mrs. Lowey, I am going to allow you to burn up the rest of the time. You kind of win the lottery today. I did intend to close the hearing at 12:30, which does not afford enough time for the rest of us to do a second round, so if you want to continue the questioning so that we can get a complete answer from everyone.

Mr. SHERER. I just wanted to quickly comment——

Mr. REHBERG. No, you do not have to hurry because you have got——

Mrs. LOWEY. The statin?

Mr. SHERER. On the statin comment, because there was actually a discussion before about a role related to repositioning, and the role that someone like NCATS can play. There is a lot of data that shows that taking a statin could decrease your risk of Parkinson's including Zocor.

So, someone should do a trial to test that as a treatment for Parkinson's disease. The patent is going to run out. Who is motivated to do it? This is a role that the government can play in something like that, you know, broadly across different diseases.

Mrs. LOWEY. Well, let me say this, because I do not want to get into personal situations. Some of us have been taking statin for years. The recent reports about diabetes and losing mental acuity are of great concern, and yet you do not want to go have a heart attack or something else in the meantime.

So, the question is, when this information is released—I probably should ask the NIH about it, too—how carefully is that information—you want to answer. I would rather hear from you. You know what I want to know.

Dr. KOENIG. Yeah. I mean, I have a couple of answers to several of the questions. This drug has been given to so many people. Let us be very clear. Every drug has side effects, and the question is, do they have a frequent occurrence or a rare occurrence? And ultimately the way we are forced to make these decisions is to expose millions of patients to get a rare occurrence to find this thing.

And so ultimately, the population has to understand this is not a risk-free situation, that there is a balance between the salutatory properties of a drug and potential side effect profiles.

Having said this——

Mrs. LOWEY. Are you on statins?

Dr. KOENIG. Yes, I am. I have been taking statins for 15 years.

Mrs. LOWEY. Which one? [Laughter.]

Dr. KOENIG. Actually the Merck compound. Okay.

Mr. REHBERG. I may call this to a close.

Mrs. LOWEY. But we do not have any good studies as to adverse reactions.

Dr. KOENIG. But let me——

Mr. REHBERG. Please either ask——

Dr. KOENIG. So, let me finish, I am sorry——

Mr. REHBERG. To claim time or go through the chair. I will maintain control of this committee.

Mrs. LOWEY. Thank you. I just was seriously asking the question because among all of us, there have been many discussions, so we were using this opportunity.

Dr. KOENIG. So, I just want to finish off is that, again, what was described today in terms of predictive toxicology to be able to now find those rare safety events in the laboratory as opposed to exposing millions of patients would be a major advance that NCATS could do in their initiative.

I have other comments on the other things, but it is——

Mr. REHBERG. That will be——

Mrs. LOWEY. Thank you, Mr. Chair.

Mr. REHBERG. Thank you very much. Thank you all for your insight. So I get this correct, and I will read this. We will hold the record open for 14 days for the subcommittee members to submit questions for the record.

In addition, I understand the NIH's center directors have submitted statements for the record. We will distribute them to subcommittee members and include them in the record.

[The prepared statements and biographies of the National Institutes of Health, Institute and Center directors follow:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Harold Varmus, M.D.
Director, National Cancer Institute

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Cancer Institute (NCI) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NCI budget of $5,068,864,000 includes an increase of $2,717,000 over the comparable FY 2012 level of $5,066,147,000.

As many of you will read when it is released next week, the 2012 Annual Report to the Nation on the Status of Cancer is expected to offer a generally encouraging view of cancer trends. The Report is informed in large part by NCI's Cancer Statistics Review, and our review shows that death rates from all cancers combined for men, women, and children in the United States continued to decline between 2004 and 2008, the latest year for which we have complete analysis. Age-adjusted mortality rates for 11 of the 18 most common cancers among men and for 14 of the 16 most common cancers in women have declined. The overall rate of new cancer diagnoses, also known as incidence, among both men and women also declined over similar periods, although for women the decline leveled off from 2006-2008.

These continued declines in death rates for most cancers, as well as the overall drop in incidence, are powerful evidence that our nation's investment in many fields of cancer research produces life-saving approaches to cancer control. The breadth of the nation's cancer portfolio and our ability to pursue many different approaches to cancer research must match the heterogeneity of cancer itself, which we now understand to be literally hundreds of genetically distinct diseases with many avenues to prevention, screening, diagnosis, and treatment.

BASIC SCIENCE

A large part of the NCI basic research portfolio uses molecular biology and genetics to deepen our knowledge about the origins and behavior of cancers and to develop drugs and understand drug resistance. For example, decades of basic research culminated in development of the molecularly targeted drug Gleevec (imatinib). Since FDA approved the drug in 2001, it has been the treatment of choice – and a very effective one – for CML, or chronic myelogenous leukemia, as well as a few other cancers. Targeted drugs usually inhibit enzymes – in this case, kinases – that are essential to the survival of cancer cells, rather than broadly killing all rapidly dividing cells in the body. In CML, the target is the abnormal protein made by fused genes, BCR-ABL, in cancerous

blood cells, where in its activated or "on" state the mutant enzyme pushes white blood cells into overdive, causing disease. Gleevec blocks the mutant enzyme, kills cancer cells, and returns the blood system and the patient to a normal state.

But despite Gleevec's generally powerful effects, some CML patients relapse when new mutations make the BCR-ABL protein resistant to Gleevec, allowing the abnormal enzyme to drive white blood cell growth again despite treatment. This phenomenon, drug resistance, is now being encountered with the several other targeted therapies more recently introduced for lung cancer, melanoma, and other cancers. So it is encouraging to report that NCI-supported research has identified a number of drugs targeting BCR-ABL proteins even after they acquire mutations that confer resistance to Gleevec. Two of these, approved a few years ago, did not overcome one relatively common resistance mutation. But a third generation of drugs is able to do that, in an interesting new way, by freezing the target protein in an inactive conformation, so that its enzyme cannot work. This example illustrates another important point. Many different research streams – from genetics to structural biology to pharmacology – were required for these advances in treatment. The need to bring together multidisciplinary teams to focus on key questions like drug resistance in cancers increasingly defines modern biomedical research.

To strengthen NCI's ability to drive similar discoveries, NCI this year consolidated a number of its genomics initiatives – including the flagship program TCGA (The Cancer Genome Atlas) – into a single Center for Cancer Genomics. TCGA's aim is to characterize comprehensively the genomic alterations in hundreds of samples of about 20 known tumor types. With the project nearing completion on schedule, the vast influx of data promises to dramatically alter our knowledge of the genetic changes that drive cancer development. The new Center will work with other components of NCI to ensure that the findings are applied to developing new diagnostics and therapeutics and are integrated swiftly into medical practice.

SCREENING AND PREVENTION

Early detection of cancer can enhance therapy. Last year I briefed this Subcommittee on the recently concluded National Lung Screening Trial, which had demonstrated that current and former smokers who were screened with low-dose helical computed tomography were 20 percent less likely to die of lung cancer compared to others who received standard chest x-rays.

Recent findings from another long-term study also point to screening as an effective way to cut deaths from another common cancer – colorectal adenocarcinoma, which kills about 49,000 Americans every year. Clinical studies, several funded by NCI, have consistently demonstrated that tests for fecal blood and direct observation of the colon with endoscopy can effectively reduce the mortality rates associated with colorectal cancer – by up to 50 percent, according to one recent estimate. NCI also is investing in studies to understand behavioral and economic barriers to screening to increase screening rates, especially among minority populations.

DIAGNOSIS AND TREATMENT

One of the most critical aspects of cancer is its remarkable heterogeneity – cancer is actually a collection of hundreds of genetically distinct diseases, each with its unique vulnerabilities. Lung adenocarcinomas, for instance, develop through a variety of genetic changes, and each pattern of changes requires a different therapeutic approach. Just a few years ago, it was recognized that up to 7 percent of lung adenocarcinomas contain a fused chromosome that activates the protein made by a gene called *ALK* to cause cancerous growth. FDA last fall approved crizotinib to treat patients with the abnormal *ALK* gene. Crizotinib blocks the activity of the enzyme, again a kinase, produced by the fused *ALK* gene, similar to the action of Gleevec in CML. This oral drug has been approved by the FDA and must be used with a companion molecular test to make sure it is used to treat only tumors with the abnormal ALK gene.

Another potential treatment recently emerged from academic research laboratories, this one for metastatic prostate cancer. MDV-3100 is a so-called anti-androgen therapy that prevents male hormones from stimulating the growth of prostate cancer cells through androgen receptors – preventing testosterone from binding to androgen receptors and preventing the androgen receptor from initiating the production of proteins that induce tumor growth. Current anti-androgen drugs suppress the growth of prostate cancer cells temporarily, but in most patients the cancer ultimately develops resistance to these drugs by increasing the amount of receptors. MDV-3100, by contrast, binds so tightly to the androgen receptors that it prevents them from functioning even when the receptor numbers are very high. The new drug performed so well that the clinical trials were halted early, and the drug now awaits approval at FDA.

PROVOCATIVE QUESTIONS

During the past 14 months, NCI has brought together researchers to propose, craft, and debate what they consider to be the critical questions in cancer research that may fall outside our current sphere of focus, but that could lead to important discoveries about the causes and behaviors of cancers. NCI convened 17 workshops across the country that identified some 24 Provocative Questions, and NCI has set aside an initial $15 million from its FY 2012 budget to fund some of the more than 750 applications received under this program. While this initiative does not replace the NCI's longtime and essential emphasis on funding investigator-initiated research, it represents a useful new approach to making the greatest impact with our research dollars.

Congress' past investments in cancer research are the reason we are able to report promising scientific findings each year, and why the Reports to the Nation continue to show steady progress against a wide range of cancers. We are now able to define genetic changes that cause cancer, use them to control cancer with more precise tools, and thereby reduce the Nation's cancer burden. The President's budget for 2013 for the National Cancer Institute will provide the support for discoveries in basic science, cancer

control and prevention, for early detection and diagnosis, and for methods to prevent, treat, and in some instances cure, cancers.

Harold Varmus, M.D.
Director, National Cancer Institute

Harold Varmus, co-recipient of a Nobel Prize for studies of the genetic basis of cancer in 1989, became Director of the National Cancer Institute on July 12, 2010, after 10 years as President of Memorial Sloan-Kettering Cancer Center, following six years as Director of the National Institutes of Health. He is a member of the U.S. National Academy of Sciences and the Institute of Medicine and is involved in initiatives to promote science in developing countries. The author of over 350 scientific papers and five books, including a recent memoir titled The Art and Politics of Science, he was a co-chair of President Obama's Council of Advisors on Science and Technology, a co-founder and Chairman of the Board of the Public Library of Science, and chair of the Scientific Board of the Gates Foundation Grand Challenges in Global Health. In 2001, he received the National Medal of Science.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Susan B. Shurin, M.D.
Acting Director, National Heart, Lung, and Blood Institute

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NHLBI budget of $3,076,067,000 includes an increase of $709,000 over the comparable FY 2012 level of $3,075,358,000.

The NHLBI leads research and education programs to discover and apply knowledge to improve health by preventing and treating heart, lung, and blood diseases. I appreciate the opportunity to highlight just a few examples of our success in doing so and some of our most promising research programs that will enable further advances.

CHRONIC DISEASE RISK REDUCTION

Cardiovascular diseases (CVD) and pulmonary conditions are among the leading causes of disability and death around the world. Although their prevention and treatment have improved dramatically, without further progress they will continue to impose an increasing health burden as our population ages. A recent meta-analysis of lifetime risk for CVD underscored the availability of lifelong opportunities for CVD prevention. The Institute is funding a clinical trial to examine diet and exercise interventions to improve neurocognition in patients with CVD risk factors who have cognitive impairment. Effective ways to help people lose weight and sustain weight loss were identified in an NHLBI-supported study reported in November 2011; multiple ongoing projects are addressing ways to help children and adults in a wide range of circumstances improve their health through weight control and physical activity.

The NHLBI continues to focus upon understanding CVD risk in vulnerable populations. The Jackson Heart Study is addressing the biological, behavioral, and psychosocial factors that account for the high burden of CVD in African Americans. The Hispanic Community Health Study–Study of Latinos is addressing the factors involved in the prevalence and development of CVD in Hispanic populations in the U.S. Both studies are expected to be renewed in FY 2013. A new program planned for FY 2013 will foster development of effective and sustainable public health interventions to reduce CVD morbidity and mortality in high-risk rural populations.

INTERPRETING THE HUMAN GENOME IN HEALTH AND DISEASE

Data from the NHLBI's substantial investment in whole exome sequencing of participants in its long-term cohort studies is paying off: data are now being deposited in dbGaP, the informatics resource at the National Library of Medicine, for use by investigators around the world. The return on this investment will provide valuable new diagnostics and treatments for the next decade.

The NHLBI has led multiple global consortia in sharing data and encouraging analysis of large genomic data sets linked to phenotype. One such consortium identified 16 genetic loci important for control of blood pressure that are now being explored by other NHLBI-supported investigators as new approaches to control blood pressure. Still other NHLBI-supported studies are revealing the genetic and environmental causes of chronic obstructive pulmonary disease (COPD), asthma, abnormalities of heart rhythm, and factors that affect the severity of hemoglobin disorders such as sickle cell disease.

NEW THERAPIES FOR HEART, LUNG, AND BLOOD DISORDERS

The NHLBI supports development of improved therapies for heart disease through resources such as the Cardiac Translational Research Implementation Program (C-TRIP) and their assessment in clinical trials through Institute-initiated programs such as the Pediatric Heart Network (now completing a trial in Marfan's syndrome and multiple studies of genetics and clinical management of congenital heart disease), the Heart Failure Network (conducting studies of cellular and drug therapies of heart failure), and the Cardiothoracic Surgical Trials Network (conducting comparative studies of surgical approaches).

Several NHLBI programs are advancing translation of basic scientific knowledge into new therapies. The Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases (CADET) will accelerate the development of agents for diagnosing and treating lung diseases. Investigators are partnering with other NIH Programs such as Therapeutics for Rare and Neglected Diseases (TRND) to do early-stage translational work that will be followed by NHLBI-supported clinical trials.

GENE AND CELLULAR THERAPIES

NHLBI-supported scientists recently reported success in treating hemophilia B, an inherited bleeding disorder, in several patients with a single infusion of a gene therapy that durably boosted the production of the missing clotting factor. If confirmed in other patients, this approach may allow patients to minimize or discontinue expensive treatment with replacement clotting factor.

Encouraging results from studies that use gene therapies in animal models for other diseases offer promise for the treatment of human disease. For example, a unique genetic approach of replacing the single mutated amino acid in mice cured their sickle cell disease. A new form of gene therapy for heart failure improved heart function in

pigs without apparent toxicity.

Bone marrow transplantation has been standard clinical therapy for certain diseases since the 1960s. The NHLBI is the primary institute supporting the Bone Marrow Transplant (BMT) Clinical Trials Network (CTN), with strong support from the NCI. A BMT CTN finding that use of mobilized peripheral blood stem cells rather than bone marrow substantially lowers the risk of graft-versus-host disease (an often fatal complication of BMT) has already affected practice and should lessen complications of BMT.

The NHLBI is supporting resources such as the Production Assistance for Cellular Therapies program to facilitate laboratory and clinical studies of cellular therapies to enhance healing after tissue damage caused by myocardial infarction and some forms of lung disease. Use of mesenchymal stem cells to repair tissue without scarring is being tested in early-stage human trials, with some very encouraging results.

RARE DISEASES

The NHLBI supports infrastructures – registries, clinical trial networks, and biorepositories – to enable research on rare diseases and on risk factors for more common diseases. For example, both sporadic and Marfan-associated thoracic aortic disease may have a common pathway, and a genetic cause of aortic aneurysms may be more prevalent than previously thought. The NHLBI is a leader in conducting clinical trials in pulmonary hypertension and idiopathic pulmonary fibrosis. Linkage of genetic and clinical data with a biorepository is enabling identification of factors influencing the development of congenital heart disease.

Following promising studies in mice, the NHLBI is now completing a study of losartan, an FDA-approved antihypertensive drug, in Marfan syndrome. The NHLBI supported a clinical trial that showed rapamycin (Sirolimus) stabilized lung function, reduced symptoms, and improved quality of life in patients with lymphangioleiomyomatosis (LAM), a progressive cystic lung disease in women. NHLBI partnerships with patient advocacy organizations in the conduct of both trials facilitated their rapid enrollment and completion.

Sickle cell disease remains an area of intensive focus for the NHLBI. A trial recently demonstrated that hydroxyurea, known to be an effective treatment for adults, is also safe and effective in very young children. In FY 2013, the NHLBI plans to initiate Excellence in Hemoglobinopathy Research Awards to promote multidisciplinary basic and translational research and facilitate collaboration with clinical hematologists. The NHLBI has played a major role in an HHS-wide initiative to coordinate the research and health care delivery efforts of six HHS components to reduce the health burdens of hemoglobinopathies (sickle cell disease and thalassemia). The NHLBI is developing clinical practice guidelines to ensure that providers know the components of high quality, evidence-based care for sickle cell disease.

HEMOVIGILANCE

The NHLBI supports multiple studies, and works closely with the FDA, to ensure appropriate monitoring of the blood supply against potential threats. In 2010 and 2011, an NHLBI-led interagency group demonstrated that a xenotropic murine retrovirus (XMRV), which had been reported to be associated with chronic fatigue syndrome in some patients, did not pose a risk to the safety of the blood supply. NHLBI leadership ensured that this and other important health questions were quickly resolved.

Susan B. Shurin, M.D.
Acting Director, National Heart, Lung, and Blood Institute

Susan B. Shurin, M.D., is Acting Director of the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), where she oversees an extensive national research portfolio with an annual budget of approximately $3 billion. The NHLBI conducts and supports research to prevent, diagnose, and treat heart, lung, and blood diseases; fosters training of emerging investigators; and communicates research advances to the public. Through the support of research from bench to bedside and into the community, Dr. Shurin leads the NHLBI's effort to transform new scientific knowledge into tangible improvements in health.

As acting director, Dr. Shurin represents the NHLBI in a wide variety of activities across the NIH and the Department of Health and Human Services. She is responsible for the basic, clinical and epidemiologic research supported and conducted by the Institute, translation of research findings to the public, and the intramural research program on the NIH campus. She has updated the NHLBI's programs in research on hemoglobinopathies, including sickle cell disease, to recruit investigators from a variety of disciplines and ensure a broad focus on implementation of research results, especially for adult patients. She created a coordinating group of HHS agencies to work with the Office of the Secretary of HHS to enhance effectiveness of research and service programs for persons with hemoglobinopathies. Dr. Shurin created and oversees the NHLBI's Global Health program, which includes a network of research projects in low- and middle-income countries building sustainable programs to combat chronic cardiovascular and lung diseases and is addressing the NHLBI's strategic scientific goals through research in domestic and international settings. She chairs the Board of the Global Alliance for Chronic Disease, national funders of biomedical research from around the world addressing the pandemic of non-communicable diseases.

Dr. Shurin joined the NHLBI as Deputy Director in February 2006, coming from Case Western Reserve University in Cleveland, Ohio. In her role as deputy director, Dr. Shurin has been involved in multiple intramural and extramural activities of the NHLBI and responsible for oversight of the Institute's clinical research portfolio. In October 2009 Dr. Shurin also assumed the role of Acting Director of the *Eunice Kennedy Shriver National Institute of Child Health and Human Development* (NICHD) while also serving as the deputy director of NHLBI.

Before joining the NHLBI, Dr. Shurin was professor of Pediatrics and Oncology at Case Western Reserve University in Cleveland, Ohio; Director of Pediatric Hematology-Oncology at Rainbow Babies and Children's Hospital; Director of Pediatric Oncology at the Case Comprehensive Cancer Center; and Vice President and Secretary of the Corporation at Case Western Reserve University.

Dr. Shurin received her education and medical training at Harvard University and the Johns Hopkins University School of Medicine. Her laboratory research focused on the physiology of phagocyte function, recognition and killing of pathogens; mechanisms

of hemolysis, red blood cell destruction; and iron overload, developing the first effective chelation therapy for chronically transfused patients with thalassemia major.

She has been active in clinical research in many aspects of pediatric hematology-oncology, including participation in the Children's Cancer Group (CCG), now the Children's Oncology Group, as well as multiple studies in sickle cell disease and hemostasis. She also served on the Executive Committee of the CCG and founded and chaired the CCG Bioethics Committee.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Martha J. Somerman, DDS, Ph.D.
Director, National Institute of Dental and Craniofacial Research

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIDCR budget of $408,212,000 includes a decrease of $2,010,000 below the comparable FY 2012 level of $410,222,000.

Science long has served as one of the Nation's most essential economic engines. From the Human Genome Project to the Internet, scientists started with basic research questions that later propelled American entrepreneurship into creating previously unimaginable new markets. So what types of research now are advancing in the Nation's laboratories and clinics that might one day propel American industry and public health to new heights? Today, I offer a brief overview of NIDCR's investment and progress in a few key areas, and suggest their potential to enhance the dental, oral, and craniofacial health of millions of Americans.

CHRONIC INFLAMMATION

A great place to start is with a promising therapeutic approach that mimics the body's own signals to control inflammation and inflammatory pain. Inflammation is part of the immune system's normal response to infections and tissue injury. Without it, tissues would not heal. At some pre-programmed point, when the threat subsides, the response turns off and inflammation is resolved. For millions of people, however, the immune system's signals get crossed and inflammation is dangerously prolonged.

An NIDCR grantee has developed promising candidate compounds based on the body's own inflammation-resolving molecules. The compounds have proven potent at reducing inflammation and inflammatory pain in animals without the adverse side effects of available analgesics. The plan is to move into human studies within the next year to evaluate their safety and efficacy in turning off the destructive inflammation occurring in periodontal disease. The hope is these compounds one day will provide a more effective approach to managing this widespread oral condition and, possibly, other chronic inflammatory conditions elsewhere in the body.

CHRONIC PAIN

The Institute of Medicine reported in 2011 that more than 116 million Americans suffer from chronic pain, with annual costs of approximately $600 million. The profound complexity of the body's processes for perceiving and responding to pain is a key factor contributing to the current inadequacies of chronic pain control and interventions to prevent the transition from acute to chronic pain. For the most part, chronic pain conditions and their molecular underpinnings remain poorly understood. This is changing. In late 2005, NIDCR began supporting the first-ever, large longitudinal clinical study of a chronic pain condition. It focuses on temporomandibular joint and muscle disorders (TMJDs), a common group of conditions that affect the area in and around the jaw joint and often overlap with other chronic pain conditions. Preliminary findings, reported in December 2011, identified mutations in genes linked to chronic TMJD, including genes associated with stress, psychological well–being, and inflammation. Building on this work, NIDCR places a high priority on supporting research on the genetics of chronic orofacial pain, with a focus on identifying gene variants that influence pain perception, their interactions with environmental triggers, and behavioral responses to pain.

In other work, NIDCR-supported behavioral scientists are providing insight into factors influencing providers' treatment decisions for chronic pain. They found that decisions tend to be influenced by individual characteristics of patients, such as gender and race or ethnicity, which are extraneous to the pain condition itself. These results are leading to new ways of training providers, helping to focus treatment decisions on more clinically relevant factors.

ORAL CANCER

Personalized health care offers tremendous promise for improving the lives of people diagnosed with cancer, as well as other diseases. Among new cancer occurrences, oral and pharyngeal cancer (OPC) is the eighth most common among U.S. men and seventh among African American men, affecting more than 30,000 people each year. Since 2009, NIDCR has invested in the Oral Cancer Genome Project, which aims to define the genetic changes driving development of oral and pharyngeal tumors. As part of this project, NIDCR-supported researchers employed next-generation sequencing technology to yield one of the most comprehensive analyses yet of the genetics underlying head and neck squamous cell carcinoma (HNSCC), the most common of OPCs. The genomics data provide evidence that HNSCC involves dozens of distinct molecular conditions, each driven by a unique pattern of gene alterations. NIDCR will support work to validate the research findings, which could help identify and reclassify these tumors based on their individual specific molecular characteristics—a key first step in establishing personalized therapies.

Another important result from the Oral Cancer Genome Project was the confirmation that head and neck tumors associated with human papillomavirus (HPV) infection have their own distinct genetic profile. HPV is associated with a subset of

OPCs that increased by 225 percent from 1998 to 2004. NIDCR supports research to understand the natural history of this growing public health issue.

The Institute also supports research to improve the survival rate for HNSCC. In a significant advance, scientists in NIDCR's laboratories demonstrated that metformin, a widely used anti-diabetes drug, prevents development and progression of oral squamous cell carcinomas in mice. NIDCR is initiating clinical studies to determine its effectiveness in humans, opening a new approach to treating this deadly cancer.

CRANIOFACIAL DEVELOPMENT

Cleft lip and cleft palate (CLP) are among the most common of all birth defects, occurring in 1 of 700 live births in the U.S., or 7,000 babies per year. Treatment is expensive and difficult, requiring multiple surgeries, orthodontics, and speech therapy over a period of years. NIDCR takes a multi-pronged approach to these devastating conditions, incorporating basic research with prevention, treatment, and post-treatment research. The goal is fewer children born with CLP, better outcomes for those afflicted with the disorders, and less cost and stress for families.

Through genome-wide studies, NIDCR-supported investigators defined several genetic and environmental CLP risk factors. This work set the stage for a researcher co-funded by NIDCR and NICHD to develop a mouse model that closely mimics CLP. The same researcher demonstrated that restoring function in one molecule resulted in complete correction of a cleft lip defect in mouse embryos still developing in utero.

NIDCR-funded investigators have found that many children born with CLP have impaired cognitive functioning that goes undetected until the child is older and remediation is more difficult. Early screening for cognitive deficits in children with CLP may help them reach their full potential through timely, tailored instruction. Research on early screening technologies is underway. In addition, NIDCR continues to fund research to optimize care for children with clefting disorders, including clinical studies comparing the cost and effectiveness of intervention procedures.

NIDCR's investment in small business innovation research (SBIR) and small business technology transfer (STTR) programs is sparking economic activity and improving outcomes for people with craniofacial defects such as CLP. An NIDCR grantee developed surgical simulation software to help clinicians plan and optimize craniofacial surgery and provide a 3D prediction of patients' outcomes. Another grantee leveraged SBIR/STTR investments to patent a minimally invasive surgical instrument system to aid periodontal surgery, often needed by people with CLP.

EVIDENCE-BASED CARE

NIDCR efforts to strengthen the knowledge base for dental practice will accelerate in April 2012 with the establishment of a National Dental Practice-Based Research Network. Building on the success of precursor regional networks, the national

network will leverage the power of large numbers of practitioners to propose and perform clinical studies on topics important to dentistry. Because the research is conducted in the real-world environment of dental practice, dentists are more likely to accept and adopt the findings. The expected result is nothing short of a transformation of dental practice – one that will result in more individualized and evidence-based treatment and prevention, to the benefit of millions of Americans.

Martha J. Somerman, DDS, Ph.D.
Director, National Institute of Dental and Craniofacial Research

Martha Somerman, D.D.S., Ph.D. became the Director of the National Institute for Dental and Craniofacial Research in August 2011, after serving as the Dean of the University of Washington School of Dentistry from 2002 – 2011.

Dr. Somerman's own research laboratory has focused on defining the key regulators controlling the development, maintenance and regeneration of tissues that form the dental-oral-craniofacial complex. In addition, her laboratory studies the appropriate cells, genes (factors), and scaffolds needed to rebuild periodontal structures lost through disease.

Dr. Somerman has published more than 120 peer-reviewed articles and serves on several editorial boards, including those of the Journal of Dental Research and International Journal of Oral and Maxillofacial Implants. She has served on committees for the American Association for the Advancement of Science (AAAS) and the IADR/AADR (International/American Association for Dental Research). In addition, she has served on the Legislative Advisory Committee of the American Dental Education Association, advising on public policy in the areas of dental and biomedical research, education and training, access and disparities in care, and infrastructure and workforce. She has also served on the American Dental Association's Council on Scientific Affairs.

Among Dr. Somerman's awards and honors are the William K. and Mary Anne Najjar Professorship at the University of Michigan, which she held from 1992 to 2002. She was named a diplomat of the American Board of Periodontology in 1990 and was president of AADR in 2001. Dr. Somerman has received the Geis Award from the American Academy of Periodontology (2003) and IADR's Distinguished Scientist Award for Research in Oral Biology (2005). In 2010, she received the IADR/Straumann Award in Regenerative Periodontal Medicine. From 1999 to 2002, she was a member of the National Advisory Dental Research Council of NIH/NIDCR. In addition, Dr. Somerman is a Fellow of AAAS, the International College of Dentists, and the American College of Dentists.

Dr. Somerman earned her B.A. in biology from New York University (NYU) and her M.S. in environmental health from Hunter College. She returned to NYU in 1975 to earn her D.D.S, specializing in periodontology and pharmacology at the Eastman Dental Center and University in Rochester, NY, earning a certificate in periodontics (1978) and Ph.D. in pharmacology (1980).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases

Mr. Chairman and Members of the Committee:

I am pleased to present the President's Budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 budget includes $1,792,107,000, which is $2,798,000 below the comparable FY 2012 appropriation of $1,794,905,000. Complementing these funds is an additional $150,000,000 also available in FY 2013 from the Special Statutory Funding Program for Type 1 Diabetes Research. The NIDDK supports research on a wide range of common, chronic, costly, and consequential diseases and health problems that affect millions of Americans. These include diabetes and other endocrine and metabolic diseases; digestive and liver diseases; kidney and urologic diseases; blood diseases; obesity; and nutrition disorders.

BUILDING NEW OPPORTUNITIES: BASIC RESEARCH DISCOVERIES

From in-depth exploration of fundamental biologic processes, NIDDK-supported scientists are achieving remarkable advances and building the foundation for previously unimaginable strategies to improve health and quality of life. Among these advances, recent NIDDK-supported research into genetic risk factors for diabetes, inflammatory bowel disease, obesity, liver disease, and the kidney disease focal segmental glomerular sclerosis, along with other studies are providing insights into disease development and whether an individual is likely to respond to a given therapy. Investigating the different types of bacteria that reside in the intestines, researchers have discovered surprising links to obesity, inflammatory bowel disease, fatty liver disease, and other health conditions. Scientists supported by our Institute are also designing novel intervention strategies and testing these in pre-clinical, laboratory models. For example, pursuing a treatment for fecal incontinence, researchers used tissue engineering to build muscle implants in mice with promising initial results, providing hope for future therapeutic use in people. Other scientists examined a potential drug for the rare disease Neimann-Pick type C in experiments with isolated human cells, and found encouraging results.

We will continue support for basic research across the Institute's mission, to gain further insights into health and disease and propel new ideas for interventions. Examples include research to identify type 2 diabetes risk genes in minority populations disproportionately affected by this disease; to discover environmental factors that trigger type 1 diabetes in genetically susceptible individuals; to elucidate the causes and consequences of a form of diabetes that can strike people with cystic fibrosis; to increase

understanding of intestinal stem cells, which could benefit a variety of digestive diseases; and to augment knowledge of blood cells and hematologic diseases.

PREVENTING AND TREATING DISEASE—IN CLINICS AND COMMUNITIES

Through innovative design and rigorous testing of interventions—whether in the operating room, doctor's office, or home or community settings—NIDDK-supported researchers are improving lives with new approaches to prevent, treat, and reverse diseases and disorders. For example, investigators previously showed that intensive blood glucose control, beginning soon after diagnosis of type 1 diabetes, reduced early signs of complications; now, after an average 22-year follow-up, the researchers demonstrated that controlling blood glucose reduced the risk of developing kidney disease by 50 percent, preserving kidney function for decades. The first cystic fibrosis therapy targeting a specific molecular defect gained FDA approval. This important advance was a culmination of research supported in part by NIDDK, from the historic gene discovery (by the NIH Director) to clinical trials of the drug. With cutting-edge tissue engineering, researchers have successfully generated urethras to replace defective tissue and ameliorate urination difficulties in boys. A network of investigators found that vitamin E helps reduce fatty liver disease in children. In studies that may alert clinicians to patients with heightened need for intervention, scientists found that elevated levels of the hormone FGF-23 mark increased risk for heart disease and death in people with chronic kidney disease, while high levels of certain amino acids in the blood signify increased risk for type 2 diabetes.

Looking forward, NIDDK is committed to continuing funding for clinical research. Because many diseases within our mission disproportionately affect certain populations, we will also continue to seek insights and answers to health disparities. As just a few examples of our many clinical studies, Institute-supported scientists will conduct trials of approaches to prevent or slow the onset of type 1 diabetes, and they will press forward in developing technology to create an artificial pancreas for people with diabetes. In a new effort, the Institute is planning a comparative effectiveness study of commonly used drugs for type 2 diabetes. We will also continue a promising, long-term clinical trial of a lifestyle intervention designed to promote weight loss and improve health in obese people with type 2 diabetes. Among multifaceted efforts to meet the challenge of obesity will be a consortium studying lifestyle interventions for overweight and obese pregnant women, to improve the health of both mother and child. The Institute will continue to support clinical studies for a range of liver diseases; for example, a multicenter research network is planning trials of different treatment strategies for hepatitis B, including comparative effectiveness research. Multiple efforts will pursue approaches to combat chronic kidney disease, polycystic kidney disease, primary glomerular disease, and other forms of kidney disease and injury. We have also spearheaded an initiative encouraging studies to prevent and treat obesity, diabetes, and kidney disease in military populations. NIDDK continues to support a multi-disciplinary study in chronic urologic pelvic pain, and will support a new research network to improve measurement of the complex symptoms of lower urinary tract dysfunction in men and women and to advance clinical studies. To maximize the reach and benefits of

interventions proven successful in clinical trials, we will sustain support for translational research, to implement these in real-world medical practice and community settings, cost effectively, for diverse populations. For example, an NIDDK-funded research project provided the first demonstration that YMCAs, now officially called Ys, can deliver a group-based version of the lifestyle intervention shown to reduce type 2 diabetes in the Diabetes Prevention Program clinical trial.

SUPPORTING AN INNOVATIVE, MULTIDISCIPLINARY WORKFORCE

Research breakthroughs happen only through the efforts of a creative, well-trained workforce. Thus, NIDDK will continue programs to train and support researchers at all stages of their careers, and to ensure that we benefit from the best scientific minds. NIDDK supports summer research opportunities for underrepresented high school and college students, workshops for minority investigators and new investigators, a new initiative for professional societies to promote diversity in the research workforce, and other efforts. We will continue to support investigator-initiated projects, along with solicited research that is guided by input from expert researchers and the public.

INTEGRATING SCIENCE-BASED INFORMATION INTO PRACTICE

We will also continue to support education, outreach, and awareness programs. These efforts include materials tailored for diverse audiences and span the range of diseases within our mission, to bring vital, science-based knowledge to health care providers, patients and their families, and the general public.

In closing, NIDDK's future research investments will build upon findings from past and ongoing studies, pursue promising new opportunities, and tackle critical challenges toward innovative and more effective prevention and treatment strategies. Our research will be guided by five principles: maintain a vigorous investigator-initiated research portfolio; support pivotal clinical studies and trials; preserve a stable pool of new investigators; foster research training and mentoring; and disseminate science-based knowledge through education and outreach programs.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Griffin P. Rodgers was named Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) on April 1, 2007. He had served as NIDDK's Acting Director since March 2006 and was the Institute's Deputy Director from 2001-2009, including 2007-2009 in which he served in a dual role. Dr. Rodgers also has been chief of the Molecular and Clinical Hematology Branch since 1998; the branch is now administratively managed by NIH's National Heart, Lung, and Blood Institute.

Dr. Rodgers received his undergraduate, graduate, and medical degrees from Brown University in Providence, R.I. He performed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology/oncology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. In addition to his medical and research training, he earned a master's degree in business administration, with a focus on the business of medicine, from Johns Hopkins University in 2005.

As a research investigator, Dr. Rodgers is widely recognized for his contributions to the development of the first effective—and now FDA approved—therapy for sickle cell anemia. He was a principal investigator in clinical trials to develop therapy for patients with sickle cell disease and also performed basic research that focused on understanding the molecular basis of how certain drugs induce gamma-globin gene expression. Recently, he and his collaborators have reported on a modified blood stem-cell transplant regimen that is highly effective in reversing sickle cell disease in adults and is associated with relatively low toxicity. He has been honored for his research with numerous awards, including the 1998 Richard and Hinda Rosenthal Foundation Award, the 2000 Arthur S. Flemming Award, the Legacy of Leadership Award in 2002, and a Mastership from the American College of Physicians in 2005.

Dr. Rodgers has been an invited professor at medical schools and hospitals in France, Italy, China, Japan, and Korea. He has been honored with many named lectureships at American medical centers and has published over 200 original research articles, reviews, and book chapters and has edited four books and monographs.

Dr. Rodgers served as Governor to the American College of Physicians for the Department of Health and Human Services from 1994 to 1997. He is a member of the American Society of Hematology, the American Society of Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academy of Sciences, among others. He served as chair of the Hematology Subspecialty Board and a member of the American Board of Internal Medicine Board of Directors. He is board certified in Internal Medicine, in Emergency Medicine, and in Hematology.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Story C. Landis, Ph.D.
Director, National Institute of Neurological Disorders and Stroke

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NINDS budget of $1,624,707,000 includes an increase of $278,000 over the comparable FY12 level of $1,624,429,000. The NINDS mission is to reduce the burden of neurological diseases through research. NIH research has improved the lives of many people with neurological disorders directly and by providing the foundation for private sector research. The American Heart Association (AHA) reported that the stroke death rate decreased by 34.8% from 1998 to 2008. Better treatments are available for multiple sclerosis, epilepsy, Parkinson's, and other diseases, and genetics research has led to tests that significantly reduce the time to obtain the correct diagnosis for many rare disorders. Moreover, basic science is driving remarkable opportunities for progress. Paradoxically, however, industry is significantly reducing their investment in research on brain disorders because of the challenges brain diseases present[1]. NINDS supports a spectrum of basic, translational, and clinical research to complement and encourage private sector efforts. Because gaps in basic understanding of the normal brain or disease are most often the cause when progress against neurological disease is not forthcoming, the Institute continues to invest more than half of its resources in basic research, for which the NIH role is especially crucial.

ACCELERATING DISCOVERY

Last year, for the first time, researchers provided a molecular diagnosis for a family's inherited disease using whole genome sequencing (WGS)[2]. The disease was a type of Charcot Marie Tooth disease, a disorder that affects the body's nerves. This year WGS provided not only a molecular diagnosis but also immediate therapeutic benefit[3]. In this study, twin children had been diagnosed with dopa-responsive dystonia, a movement disorder that reflects a deficiency of the neurotransmitter dopamine. The children's health problems persisted despite treatment with the drug l-dopa, which replenishes dopamine and is usually effective. Once WGS identified the specific gene defect, it became apparent that the neurotransmitter serotonin was also deficient. Boosting serotonin with a readily available drug dramatically improved the children's health. Dozens of studies are now underway using these "next generation" sequencing

[1] The Wall Street Journal, March 27, 2011; Nature 480:161-2, 2011 (December)
[2] New England Journal of Medicine 362:1181-91 2010
[3] Science Translational Medicine 3:1-6, 2011

methods in common and rare neurological diseases. A new "Center without Walls," for example, is bringing the best researchers together, regardless of geography, to apply the new genetics technologies to epilepsy.

Next generation sequencing is just one of several technologies that are transforming basic and clinical neuroscience. Optogenetics allows precise control of nerve cells' activity by light. Induced pluripotent stem cell (iPSC) methods derive nerve cells from skin cells of patients affected by disease, to enable studies of disease and screening of drugs in a culture dish. NINDS supports extensive iPSC research, including consortia in ALS, Parkinson's, and Huntington's disease. Brain imaging now reveals structure, activity, and chemistry of the living brain in health and disease. Recently, for example, brain imaging provided insights about traumatic brain injuries (TBI) in the military, the lingering effects of concussions in young athletes[4] and new understanding of autism[5]. The NIH Human Connectome Project is an ambitious imaging effort to map the wiring diagram of the entire human brain. NIH encourages sharing of data from the Connectome project, gene studies, iPSC methods, and other research that is producing extraordinary amounts of useful information. A notable recent effort to promote data sharing is a TBI database created jointly by the NIH and the Department of Defense[6].

TRANSLATING DISCOVERY TO HEALTH

NINDS has a long history of translating scientific advances into better medicine. Rare disease studies, bold new therapeutic strategies, and technology development are examples of translational research in which NINDS plays a key role. Several NINDS programs support translational research. The Anticonvulsant Screening Program (ASP) has contributed to the development of eight epilepsy drugs now on the market. Following an external review completed this year, the ASP will refocus on what most concerns the epilepsy community today—drugs to address treatment-resistant epilepsy and to modify the course and development of the underlying disease. Recent activities in the NINDS Neural Prosthesis Program, which pioneered this entire field, include collaboration with DARPA (Defense Advanced Research Projects Agency) to enhance brain control of an advanced prosthetic arm, and development of an ultrathin flexible brain implant that could one day be used to treat epileptic seizures and other disorders[7]. To exploit opportunities across all neurological disorders, the Cooperative Program in Translational Research, begun in 2002, supports teams of academic and small business investigators to carry out preclinical therapy development. NINDS is now funding two Phase II clinical trials of therapies developed in this program. NINDS is also leading an NIH Blueprint Grant Challenge to develop truly novel drugs that will transform the treatment of nervous system diseases.

Because candidate therapies for many disorders are emerging, in 2011 NINDS launched the NeuroNext clinical network at 25 sites across the U.S. NeuroNext will

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[4] NeuroImage 55:1716-27, 2011; Neurology 74:643-650, 2010
[5] http://www.nih.gov/news/health/feb2012/nichd-21.htm
[6] http://www.ninds.nih.gov/news_and_events/news_articles/FITBIR_database.htm
[7] Nature Neuroscience 14:1599-605, 2011

remove roadblocks to the crucial early stage clinical testing of novel therapies and reduce from years to months the time to move new therapies into testing in patients. NeuroNext will test biomarkers for spinal muscular atrophy (SMA) in its first clinical study to prepare for trials of candidate therapies for SMA.

NINDS phase III, multi-center clinical trials continue to advance public health. The Neurological Emergency Treatment Trials (NETT) network completed the Rapid Anticonvulsant Medication Prior to Arrival (RAMPART) trial well ahead of schedule, showing that paramedics in the field can safely deliver the drug midazolam into muscle using an autoinjector (like an EpiPen) and stop continuous seizures faster than the usual intravenous treatment.[8] These results inform responses to common continuous seizures and seizures caused by industrial accidents or nerve agents. NETT trials of stroke and TBI emergency treatments are underway. Also this year, the Stenting vs. Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMPRISS) clinical trial showed that patients at high risk for a second stroke who received intensive medical treatment had fewer strokes and deaths than patients who received a stent in blood vessels that supply the brain in addition to the medical treatment[9]. Follow up is continuing to compare longer term benefits.

With the concern about dementia as our population ages, it is worth noting that stroke is a major contributor to dementia, highlighting the complex relationships among various types of dementia. Not only do the 7 million U.S. stroke survivors have an increased likelihood of cognitive problems, and perhaps also 13 million who have had "silent strokes" [10], but also vascular problems that cause stroke are also associated with Alzheimer's disease. Signs that a stroke has occurred are often found in the brains of Alzheimer's patients, and beta-amyloid, a key protein in Alzheimer's pathology, may stimulate the formation of blood clots, which can cause stroke[11]. Furthermore, last year the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study, which is following more than 30,000 people, reported that high blood pressure and other known risk factors for stroke increase the risk of cognitive problems, even among people who have never had a stroke[12]. Research suggests that there is a dementia spectrum from pure vascular dementia to pure Alzheimer's disease, with most patients having contributions from both[13]. Recognition of intersections not only between Alzheimer's disease and stroke, but also Alzheimer's disease with TBI, Parkinson's, frontotemporal dementia, and other disorders may provide leads toward better prevention and treatment of all dementias.

Hundreds of neurological disorders affect patients, families, and society. The aging population, concern about the long lasting effects of TBI, and reduced private sector investment are among several factors that underscore the importance of NINDS

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[8] New England Journal of Medicine 366:591-600, 2012
[9] http://www.ninds.nih.gov/news_and_events/news_articles/SAMMPRIS_trial_results.htm
[10] Circulation 125:e2-e220, 2012
[11] Neuron 66:695-709, 2010
[12] Neurology 77:1729, 2011; Annals of Neurology 70:229-36, 2011
[13] Neurology 72:368-74,2009

funded research. Although neurological disorders present enormous challenges, progress in neuroscience and other areas of research provides exceptional opportunities for the future.

Story C. Landis, Ph.D.
Director, National Institute of Neurological Disorders and Stroke

Dr. Story C. Landis began her appointment as the Director of the National Institute of Neurological Disorders and Stroke (NINDS) on September 1, 2003. A native of New England, Dr. Landis was awarded her B.A. degree in Biology, with highest honors, from Wellesley College (1967), and her M.A. (1970) and Ph.D. (1973) degrees from Harvard University. After postdoctoral work at Harvard University studying transmitter plasticity in sympathetic neurons, she served on the faculty of the Harvard Medical School's Department of Neurobiology.

In 1985, Dr. Landis joined the faculty of the Case Western Reserve University School (CWRU) of Medicine in Cleveland, Ohio, where she held many academic positions, including Associate Professor of Pharmacology, Professor and Director of the Center on Neurosciences, and Professor and Chairman of the Department of Neurosciences, a department that she was instrumental in establishing. Under her leadership, the CWRU Department of Neurosciences achieved worldwide acclaim and a reputation for excellence. In 1995, Dr. Landis was appointed as the NINDS Scientific Director, and was responsible for the direction and re-engineering of the Institute's intramural research program. Beginning in 1999, in conjunction with the leadership of the National Institute of Mental Health (NIMH), she spearheaded a movement to bring a sense of unity and common purpose to the numerous laboratories, in multiple NIH Institutes, that conduct leading edge clinical and basic neuroscience research, which increased research cooperation and collaboration, and resulted in the construction of the new NIH Neuroscience Research Center, Phase II of which is currently under construction on the NIH campus. Since early 2007, Dr. Landis has also been Chair of the NIH Stem Cell Task Force.

Throughout her research career, Dr. Landis has made many fundamental contributions to understanding the developmental interactions required for synapse formation, and has garnered many honors and awards. Dr. Landis is an elected Fellow of the American Academy of Arts and Sciences and the American Association for the Advancement of Science, and an elected member of the American Neurological Association. In 2002, she was elected President of the Society for Neuroscience, and served as President-elect until her appointment as the NINDS Director in September 2003. In 2009, Dr. Landis was elected to the Institute of Medicine of the National Academy of Sciences.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIAID budget of $4,495,307,000 includes an increase of $10,210,000 over the comparable FY 2012 level of $4,485,097,000.

NIAID conducts and supports biomedical research to understand, treat, and prevent infectious and immune-mediated diseases, including HIV/AIDS, tuberculosis, malaria, influenza, emerging and re-emerging infectious diseases, asthma and allergic diseases, autoimmune diseases, and the rejection of transplanted organs. I appreciate the opportunity to highlight our recent scientific advances and to describe some of our most promising research aimed at improving public health and quality of life.

INFECTIOUS DISEASES RESEARCH

HIV/AIDS. In the 30 years since AIDS was first recognized in the United States, the substantial NIAID investment in basic, translational, and clinical HIV/AIDS research supported consistently by this Committee has resulted in many groundbreaking discoveries. With this commitment, we have made significant progress, including strengthening HIV prevention efforts and developing nearly 30 antiretroviral drugs to suppress HIV. Thirty years ago, HIV/AIDS was for the most part a death sentence. Today, if a young person enters the clinic with early HIV disease and begins appropriate therapy, he or she can expect to live a near-normal lifespan, a milestone unimaginable at the start of the HIV/AIDS pandemic.

I am pleased to report landmark advances and opportunities in HIV/AIDS research this year. In December 2011, the journal *Science* named an NIAID-funded international HIV prevention study its *Breakthrough of the Year*, reinforcing that the investment in NIH research continues to pay extraordinary dividends for public health. This study, known as HPTN 052, demonstrated that HIV-infected heterosexual individuals who began taking antiretroviral medicines when their immune systems were still relatively healthy, rather than later, were 96 percent less likely to transmit the virus to their uninfected sexual partners. This study convincingly demonstrates that antiretrovirals not only can be life-saving to people infected with HIV, but also can prevent transmission of the virus to their uninfected sexual partners. Other studies have shown that medically supervised adult male circumcision has proven to be highly

effective and durable in preventing the acquisition of HIV infection. In addition, pre-exposure prophylaxis of at-risk uninfected individuals may be an important means of preventing HIV infection.

HIV vaccines still represent the best long-term hope for ending the HIV pandemic. Building on the promising results of the U.S. Army-NIAID RV144 HIV vaccine clinical trial, which found a "prime-boost" vaccine candidate to be safe and modestly effective at preventing acquisition of HIV, NIAID is working to understand the immune mechanisms that explain these results, to optimize the protective immune responses elicited by the vaccine candidate, and to develop and evaluate new vaccine candidates. We also are encouraged by the discovery by NIAID-supported scientists of human antibodies that can block a wide range of HIV strains. We are expanding clinical testing in this area, and insights gained from these studies will guide future HIV vaccine research.

These research advances taken together with the implementation of other evidence-based HIV prevention and treatment strategies make the possibility of an "AIDS-free generation" in the foreseeable future eminently feasible. This July, we will consider strategies to implement these important findings during the International AIDS Society Conference in Washington, D.C.

Tuberculosis and Malaria. NIAID continues to invest in basic and clinical research and collaborate with global partners, including the World Health Organization's Stop TB Partnership, to combat the co-infections that often accompany HIV infection, including tuberculosis (TB) and malaria. Building on these efforts, we now have a substantial development pipeline of TB treatments and vaccines. NIAID has developed a *Strategic Blueprint for TB Vaccines* that proposes new research pathways for achieving a licensed TB vaccine. For malaria, NIAID supported early-stage basic research that ultimately led to the development by others of the first moderately successful malaria vaccine candidate aimed particularly for children, RTS,S/AS01, a *Science Runner-Up Breakthrough of the Year* in 2011. In addition, the NIAID Vaccine Research Center is partnering with a biotechnology firm to undertake clinical studies of a novel malaria vaccine candidate, PfSPZ. NIAID also plays a leading role in the international Malaria Eradication Research Agenda initiative.

Other Infectious Diseases of Domestic and Global Health Importance. NIAID's longstanding investments in basic and clinical research have led to many successes in vaccine development for diseases of worldwide public health concern, including gastroenteritis caused by rotavirus, pneumonia, hepatitis A, and deadly meningitis caused by *Haemophilus influenzae* type b. These are among the vaccines now being delivered to countries around the world; where they have been deployed, substantial reductions in morbidity and mortality have been observed. NIAID has assumed a major leadership role in the "Decade of Vaccines" initiative, a ten-year collaborative effort coordinated by the Bill & Melinda Gates Foundation, to develop and deliver vaccines to the world's poorest countries. NIAID will continue research on other urgently needed vaccines, including vaccines for Group B *Streptococci*, Epstein-Barr virus, and hepatitis C virus.

Seasonal and pandemic influenzas remain critical global health and economic threats. NIAID has made significant progress in the development and testing of vaccines to protect people from influenza, including the elderly, young children, and those with asthma. Recently, NIAID researchers demonstrated that a "prime-boost" gene-based vaccination strategy could activate the immune system and lead to broadly neutralizing antibody responses against influenza viruses. This finding and those from other researchers signal that we are closer to developing a "universal" vaccine that could protect against multiple strains of seasonal and pandemic influenza viruses.

This year, in response to the growing public health issue of antimicrobial resistance, NIAID will expand our clinical trials networks developed originally for HIV/AIDS to investigate this important concern. In addition, NIAID will support research to determine how to preserve the effectiveness of current antibiotics.

NIAID's biodefense research has yielded numerous scientific advances as we have moved from a "one bug-one drug" approach to a more flexible, broad-based product development strategy that utilizes sophisticated genomic and proteomic platforms to address infectious disease outbreaks, whether they are deliberately introduced or naturally occurring. As part of this effort, NIAID has awarded contracts for the development of broad-spectrum therapeutics against emerging infectious disease and biodefense agents.

RESEARCH ON IMMUNOLOGY AND IMMUNE-MEDIATED DISORDERS

NIAID was highly gratified that the 2011 Nobel Prize in Physiology or Medicine was awarded to three NIAID grantees: Bruce A. Beutler, Jules A. Hoffmann, and the late Ralph M. Steinman. Their research has been pivotal in understanding the human immune response, and it is helping to inform the development of new vaccines and vaccine adjuvants that may provide better protection against infectious diseases.

NIAID's commitment to basic immunology research has led to advances in the treatment of immunological conditions such as the rejection of transplanted organs. In 2011, the *Journal of the American Medical Association* published an NIAID Immune Tolerance Network study demonstrating that children who receive liver transplants may not need lifelong anti-rejection therapy to maintain the transplanted organ. Other NIAID-supported investigators demonstrated that some kidney transplant recipients who also received bone marrow from the kidney donor can maintain their kidney grafts without immunosuppressive drugs.

CONCLUSION

NIAID basic and clinical research on infectious and immune-mediated diseases will continue to promote the development of vaccines, therapeutics, and diagnostics to improve health and save millions of lives worldwide. NIAID remains committed to

supporting highly meritorious research with the goal of translating fundamental scientific findings into public health advances.

Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases

Dr. Fauci was appointed Director of NIAID in 1984. He oversees an extensive research portfolio of basic and applied research to prevent, diagnose, and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies. Dr. Fauci serves as one of the key advisors to the White House and Department of Health and Human Services on global AIDS issues, and on initiatives to bolster medical and public health preparedness against emerging infectious disease threats such as pandemic influenza.

Dr. Fauci has made many contributions to basic and clinical research on the pathogenesis and treatment of immune-mediated and infectious diseases. He has pioneered the field of human immunoregulation by making a number of basic scientific observations that serve as the basis for current understanding of the regulation of the human immune response. In addition, Dr. Fauci is widely recognized for delineating the precise mechanisms whereby immunosuppressive agents modulate the human immune response. He has developed effective therapies for formerly fatal inflammatory and immune-mediated diseases such as polyarteritis nodosa, Wegener's granulomatosis, and lymphomatoid granulomatosis.

Dr. Fauci has made seminal contributions to the understanding of how the AIDS virus destroys the body's defenses leading to its susceptibility to deadly infections. He also has delineated the mechanisms of induction of HIV expression by endogenous cytokines. Furthermore, he has been instrumental in developing highly effective strategies for the therapy of patients with this serious disease, as well as for a vaccine to prevent HIV infection. He continues to devote much of his research time to identifying the nature of the immunopathogenic mechanisms of HIV infection and the scope of the body's immune responses to the AIDS retrovirus.

Dr. Fauci has delivered many major lectureships all over the world and is the recipient of numerous prestigious awards for his scientific accomplishments, including the Presidential Medal of Freedom, the National Medal of Science, the George M. Kober Medal of the Association of American Physicians, the Mary Woodard Lasker Award for Public Service, the Albany Medical Center Prize in Medicine and Biomedical Research, and 36 honorary doctoral degrees from universities in the United States and abroad.

Dr. Fauci is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, the Institute of Medicine (Council Member), the American Philosophical Society, and the Royal Danish Academy of Science and Letters, as well as a number of other professional societies including the American College of Physicians, the American Society for Clinical Investigation, the Association of American Physicians, the Infectious Diseases Society of America, the American Association of Immunologists, and the American Academy of Allergy Asthma and Immunology. He

serves on the editorial boards of many scientific journals; as an editor of Harrison's Principles of Internal Medicine; and as author, coauthor, or editor of more than 1,100 scientific publications, including several textbooks.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Judith H. Greenberg, Ph.D.
Acting Director, National Institute of General Medical Sciences

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIGMS budget of $2,378,835,000 includes a decrease of $48,354,000 below the comparable FY 2012 level of $2,427,189,000.

This year, in 2012, the National Institute of General Medical Sciences celebrates its 50-year anniversary as NIH's "basic research institute". Since 1962, NIGMS has continuously supported highly creative people committed to building a broad and deep foundation of discovery. The findings are used and applied by scientists everywhere, leading to new diagnostics, new therapies, and new ways to prevent a wide range of diseases.

MODEL SYSTEMS ILLUMINATE HUMAN HEALTH

Laboratory-animal versions of disease are a staple of basic biomedical and behavioral research. Because fruit flies, worms, mice, and other animals are easy and relatively inexpensive to work with--and have most of the same genes and many of the same behaviors as we do--they are valuable tools for biomedical discovery. Sometimes, though, results with animal models do not hold up in human studies, in part because organisms studied in the laboratory lack the genetic diversity of people. NIGMS has addressed this problem through its support of the Collaborative Cross, a large-scale mouse-breeding project that significantly expands the genetic diversity of mice. This project has made its resources widely available to scientists everywhere--helping to fast-track important discoveries about genetics and human disease.

Other recent studies with model systems, in this case worms, have pointed to new information about a group of neurological diseases that have a common molecular defect: the inability of normal cellular proteins to fold themselves into their proper three-dimensional shapes. Misfolded proteins are implicated in Alzheimer's, Parkinson's and Huntington's diseases, amyotrophic lateral sclerosis, cancer, cystic fibrosis, and type 2 diabetes. The recent work identified new genes and signaling pathways that keep proteins folded properly and prevent toxic clumping. The researchers also extended their findings by identifying small molecules that appear to repair misfolded proteins.

ALL SYSTEMS GO

While animal models offer key clues to understanding human disease, other studies that investigate large, interacting systems are an essential avenue for learning about health and disease. Systems biology approaches, which promote a more thorough grasp of the intricate and dynamic workings of how molecular and cellular parts interact to make a whole, is a robust area of NIGMS-funded biomedical research.

Human behavior is one example of an enormously complicated system--not just for an individual, but also between individuals and within and between populations. Systems biology research employing mathematical models can draw connections among a vast number of inputs, uncovering new connections and making new predictions. NIGMS has joined forced with the NIH Office of Behavioral and Social Sciences Research to identify opportunities, challenges, and gaps in knowledge needed to develop useful models of social behavior. This past fall, NIGMS issued a call for funding research that models social behavior. The new program has generated substantial interest in the research community, and the Institute is looking forward to the results that are likely to have broad application.

Another scientific area of great complexity, even though the subject of study is microscopic, is the interactions between viruses and their hosts. For many years, NIGMS has funded the AIDS-Related Structural Biology Program to obtain the three-dimensional structures of HIV proteins. Representing the culmination of hundreds of studies, researchers have just published a map of nearly 500 physical interactions between components of HIV and those in human cells. The research provides a gold mine for further studies into new drugs and vaccines against HIV.

ACCELERATING THE PACE OF DISCOVERY

As our world has flattened due to increased human travel and expanded commercial trade among many international partners, a number of new diseases have emerged and infected people around the world. To help the nation and the world understand and prepare for contagious outbreaks, NIGMS funds the Models of Infectious Disease Agent Study (MIDAS). This international effort continues to add new research expertise to increase its capacity to simulate disease spread, evaluate different intervention strategies, and help inform public health officials and policymakers. In 2011, MIDAS scientists used whole-genome sequencing to trace the path of the *E. coli* outbreak that made thousands of people ill and killed over 50 people in Germany and France. The project demonstrates the power of modeling and is one of the first uses of genetic detective work to study the dynamics of a food-borne outbreak.

The NIGMS investment accelerates the pace of discovery through its support of chemistry projects that enable biologists to study cells and organisms using state-of-the-art chemical tools; help clarify the chemical reactions that underlie human metabolism; and provide new strategies for drug development. NIGMS-supported chemists recently made two new discoveries that should enhance the manufacture of key drugs. In the first

study, scientists made significant progress toward a simpler, more efficient way to synthesize Taxol, an important cancer drug used routinely to treat ovarian, breast, lung, liver, and other cancers. In a second study, NIGMS-funded chemists unveiled the working parts of the commonly used anti-fungal medicine amphotericin B, nicknamed by physicians "ampho-terrible" for its harsh side effects. The new work opens up possibilities for designing similar anti-fungal medicines that are just as effective but easier on the body.

INVESTING IN THE FUTURE OF DISCOVERY

The Institute believes that a strong biomedical research workforce is essential for the tandem goals of improving health and maintaining global competitiveness. In 2011, NIGMS published "Investing in the Future: the NIGMS Strategic Plan for Biomedical and Behavioral Research Training". Implementation of this plan is now in full swing. Going forward, NIGMS has articulated clearly that research training is a partnership between the NIH and the academic community and continues to engage actively with its full range of stakeholders. Key foci include the importance of excellent mentoring, a continuing emphasis on diversity, and the need to recognize a full menu of career options beyond academic research for newly trained scientists.

NIGMS has also recently established a new organizational component, the Division of Training, Workforce Development, and Diversity, which integrates training, diversity, and capacity-building activities across Institute programs. This new component also oversees the Institutional Development Award (IDeA) program that broadens the geographic distribution of NIH funding. A new component of this effort is the IDeA Program Infrastructure for Clinical and Translational Research initiative, which encourages applications from IDeA states to develop infrastructure and capacity to conduct clinical and translational research on diseases that affect medically underserved populations and/or diseases prevalent in these 23 states and territories traditionally underfunded by the NIH.

EXTENDING THE REACH OF BASIC RESEARCH

Within the clinical realm, NIGMS continues to support the NIH Pharmacogenetics Research Network (PGRN), now in its 12th year of funding. This endeavor has yielded a bounty of medically relevant knowledge, including how genetic information can help predict how heart drugs, cancer medicines, nicotine patches, and a range of other treatments are likely to work in a particular person. One PGRN project is now partnering with the Electronic Medical Records and Genomics (eMERGE) Consortium to test samples from people whose electronic medical records are also available to the researchers. The goal is to demonstrate that DNA differences can be useful for decision-making about drug type and dosage, and ultimately to improve medication safety and efficacy.

Judith H. Greenberg, Ph.D.
Acting Director, National Institute of General Medical Sciences

Judith H. Greenberg, Ph.D., became acting director of the National Institute of General Medical Sciences on July 12, 2011.

In this position, she oversees the Institute's $2 billion budget, which primarily funds basic research in cell biology, biophysics, genetics, developmental biology, pharmacology, physiology, biological chemistry, bioinformatics and computational biology. NIGMS supports more than 4,500 research grants—about 10 percent of the grants funded by NIH as a whole—as well as a substantial amount of research training and programs designed to increase the diversity of the biomedical and behavioral research workforce.

A developmental biologist by training, Greenberg has directed the NIGMS Division of Genetics and Developmental Biology since 1988. In Fiscal Year 2010, the division's budget was $566 million.

Since 1984, Greenberg has been the project officer for the Human Genetic Cell Repository, which provides cell lines and DNA samples to scientists studying genetic diseases. She has been instrumental in overseeing the evolution of the collection to anticipate and meet the needs of the human genetic research community.

She served as NIGMS acting director once before, from May 2002 to November 2003.

Greenberg's other leadership roles at NIGMS include overseeing the development of the Institute's strategic plan issued in 2008 and its strategic plan for research training issued in 2011. She now chairs the implementation committee for the training strategic plan.

Her strong interest in bioethical issues related to genetics led Greenberg to hold the First Community Consultation on the Responsible Collection and Use of Samples for Genetic Research in September 2000. In addition, she chaired an NIH working group on community consultation in genetic research, which issued a document entitled "Points to Consider When Planning a Genetic Study that Involves Members of Named Populations." She currently serves on the NIH Bioethics Task Force.

Greenberg has also advised NIH on human embryonic stem cells and gene therapy. She has served as principal leader of the NIH Director's Pioneer Award program since 2004 and of the NIH Director's New Innovator Award program since its inception in 2007.

Greenberg was the NIH program representative to the Federal Demonstration Partnership from 1991 to 1998 and was a member of its executive committee from 1996 to 1998. Prior to joining NIGMS as a program administrator in 1981, Greenberg

conducted research in the intramural program of what is now the NIH's National Institute of Dental and Craniofacial Research. Her focus was on cell migration and differentiation in early embryonic development.

Greenberg's honors include a Public Health Service Special Recognition Award in 1991 and a Presidential Meritorious Executive Rank Award in 1999. Her leadership of the Pioneer and New Innovator Award programs was recognized with NIH Director's Awards in 2006 and 2008, respectively.

Greenberg earned a B.S. degree in biology from the University of Pittsburgh, an M.A. degree in biology from Boston University and a Ph.D. degree in developmental biology from Bryn Mawr College.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Alan E. Guttmacher, M.D.
Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Mr. Chairman and Members of the Committee:

I am pleased to present the FY 2013 President's Budget Request for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) of $1,320,600,000. The Fiscal Year (FY) 2013 NICHD budget reflects an increase of $775,000 over the comparable FY 2012 level of $1,319,825,000.

50 YEARS OF CONTRIBUTIONS TO HEALTH

This year marks the 50th anniversary of the founding of the NICHD. Thanks to continuing Congressional support and the unwavering dedication of our scientists and stakeholders, NICHD research has changed the lives of women, children, families, and those individuals with disabilities worldwide. Since the NICHD was established in the early 1960s, research supported by the Institute contributed to a 50 percent drop in sudden infant death syndrome (SIDS), and a 70 percent drop in respiratory distress syndrome, both leading causes of the nation's infant mortality rate. Transmission of HIV from infected mother to fetus dropped from 25 percent to less than one percent in the past 15 years. Discovery of an early biological marker of pregnancy led to the development of what is now the standard pregnancy test. The incidence of Haemophilus influenzae type b (Hib) meningitis, once the leading cause of acquired intellectual disability, has dropped more than 90 percent with the development of the Hib vaccine by NICHD scientists. Beyond these past contributions to public health, our anniversary presents a unique opportunity to catalyze scientific advances.

NEW ADVANCES CONTINUE THE MOMENTUM

The NICHD's basic research, conducted on the NIH campus and supported at academic institutions nationwide, adds to scientific knowledge and enables clinical researchers to develop and test new treatments. For example, in Type 1 diabetes, the immune system destroys the body's insulin-producing cells that help control blood glucose levels. Infertility researchers funded by the NICHD found a way to convert endometrial stem cells into insulin-producing cells and transplant them into mice to control diabetes. These findings suggest that ultimately, a woman's own, readily available, endometrial stem cells could be used to develop insulin-producing islet cells, minimizing the chance of rejection posed by using tissues or cells from another person.

Research shows promise for developing new treatments for uterine fibroids. These non-cancerous tumors, three to four times more common in African American than white women, are often associated with chronic pain, infertility, and preterm labor. Currently, few treatment options exist except surgical removal of the uterus (hysterectomy). A recent NICHD-sponsored analysis concluded that the economic costs of the poor health outcomes, treatment, and management of fibroids in the U.S. may reach $34 billion annually. Other NICHD-supported researchers found that treatment with vitamin D reduced the size of uterine fibroids in laboratory rats predisposed to developing the tumors, suggesting that differential rates of Vitamin D deficiency could help explain the health disparities in fibroid formation. Another approach, using a drug to shrink the tumors, has shown promise in preliminary clinical studies.

New technologies and tools are allowing the research community to move science along faster than ever. For example, a NICHD-supported physiatrist is combining bioengineering with a technique called "targeted muscle reinnervation," using nerves that remain after amputation to control assistive devices; this has enabled researchers to link an individual's brain impulses to a computer in a prosthesis that directs motors to move the limb. The NICHD small business innovation research (SBIR) program has supported development of emerging technologies to address mounting concerns about the effects of concussions. Scientists have created a device mounted inside a football helmet to measure the impact of a collision. This new tool has already helped to quantify the impact of concussions for college football players, determine how head injuries may differ for football players at different positions, and can be used to design more protective helmets.

Scientists at the NIH's Autism Centers of Excellence are taking advantage of new insights into brain structure and function in their Infant Brain Imaging Study. Using a special imaging technique, they tracked the brain development of infants and toddlers who have an older sibling with an autism spectrum disorder (ASD), and thus, are at increased risk of developing ASD themselves. The researchers found distinctly different patterns of brain development in the younger siblings who were later diagnosed with ASD compared to those who weren't. These findings represent the earliest age (six to 24 months) at which such biomarkers for ASD have been identified.

It is especially gratifying when scientific advances like these are put into practice. Last year, I reported on a major new study supported by the NICHD demonstrating that fetal surgery to correct myelomeningocele (spina bifida) greatly reduced the risk of death and doubled the chances of children being able to walk, compared to the standard practice of postnatal surgery. Over the past year, the NICHD has convened a series of meetings with numerous leading professional societies to ensure sufficient and consistent training and guidelines for performing this highly complex procedure as it becomes available in various sites around the country.

In late 2011, an NICHD-supported analysis of over five million medical records showed that pregnant women assaulted by an intimate partner are at increased risk of giving birth to infants at lower birth weights. Babies born at low birth weights are at

higher risk for SIDS, heart and breathing problems, and learning disabilities. The American College of Obstetricians and Gynecologists used this information in developing physician training materials for screening patients for intimate partner violence.

Since 2002, the NICHD has led the NIH's implementation of the Best Pharmaceuticals for Children Act, supporting pharmacokinetic research and new clinical trials on drugs not previously tested for pediatric use. Due in large part to the NICHD's Pediatric Trials Network, data on pediatric safety, dosing, and efficacy for several common drugs were sent to the Food and Drug Administration this year so that the drugs' labels can be changed, and the children potentially benefiting from these therapeutics can be treated appropriately.

LOOKING AHEAD: SCIENTIFIC VISIONING

As exciting as these advances are, we know that the promise of improving the nation's health depends on enlightened management of the research enterprise. The NICHD has just concluded a "visioning" process to help us focus over the next ten years on the best ways to achieve scientific goals, enhance prevention, and continue to improve the nation's health. After in-depth consultation with over 700 experts from around the country, white papers covering nine major areas of our science were made available online (http://www.nichd.nih.gov/vision), and a scientific commentary summarizing NICHD's overall vision will appear in a major medical journal later this year. Now the NICHD looks to the future, where we will work with our research partners to detail how genes, the environment, and behaviors interact, starting before birth, to affect health outcomes. We plan to determine all the causes of preterm birth, devise new treatments to maximize gynecologic health, and improve the health and functioning of individuals with intellectual, developmental, or physical differences. Collaborative efforts to strengthen transdisciplinary research and enhance the ways that we conduct science will be essential to this future.

CONCLUSION

Whether they work at the NIH or receive grants at academic institutions across the country, NICHD-supported scientists are an invaluable national resource. In the past year alone, two long-time NICHD grantees were among only seven researchers named by President Obama as recipients of the National Medal of Science. And, to honor her work encouraging young women from the inner city to engage in scientific research careers, a third NICHD grantee was recently awarded the Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring. It is with the help of exceptional individuals such as these, and your support, that we will embark on the next fifty years of the NICHD's "Research for a Lifetime".

Alan E. Guttmacher, M.D.
Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

In August 2010, Alan E. Guttmacher, M.D. became the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. Previously, he served as Acting Director of the Institute, beginning in December 2009. A pediatrician and medical geneticist, Dr. Guttmacher came to the National Institutes of Health in 1999 to work at the National Human Genome Research Institute (NHGRI), where he served in a number of roles, including seven years as the Deputy Director and, from August 2008 to December 2009, as the Acting Director. In those roles, he oversaw the institute's efforts to advance genome research, integrate that research into health care, and explore the ethical, legal, and social implications of human genomics.

Dr. Guttmacher also previously served as the Senior Clinical Advisor to the Director of NHGRI and as Director of NHGRI's Office of Policy, Communications, and Education, leading the institute's health affairs, public policy, communications, community outreach, and public education functions. He led the institute's involvement in educating both the public and health professionals about genomics and genomic healthcare. Among Dr. Guttmacher's areas of expertise is the development of new approaches for translating the findings of the Human Genome Project into better ways of diagnosing, treating, and preventing disease. He oversaw NIH's involvement in The U.S. Surgeon General's Family History Initiative, an effort to encourage all Americans to learn about and use their families' health histories to improve health. He served as co-editor for a series of articles about genomic medicine that was published in the *New England Journal of Medicine* in 2002-2003 and is currently co-editing a follow-up series in the same journal.

Dr. Guttmacher came to the NIH from the University of Vermont, where he directed the Vermont Regional Genetics Center and Pregnancy Risk Information Service, the Vermont Newborn Screening Program, and the Vermont Cancer Center's Familial Cancer Program. He also founded Vermont's only pediatric intensive care unit, and was the principal investigator for an NIH-supported initiative that was the nation's first statewide effort to involve the general public in discussion of the Human Genome Project's ethical, legal, and social implications. Throughout all of these activities, Dr. Guttmacher conducted research, taught, and had a busy practice in clinical genetics. His own research has centered around understanding the biology and natural history of rare diseases, particularly hereditary hemorrhagic telangiectasia (HHT), and finding ways to improve the well-being of people with them.

A graduate of Harvard College and of Harvard Medical School, Dr. Guttmacher completed an internship and residency in pediatrics and a fellowship in medical genetics at Harvard and Children's Hospital of Boston. He is a member of the Institute of Medicine and a Fellow of the American Academy of Pediatrics.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Paul A. Sieving, M.D., Ph.D.
Director, National Eye Institute

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Eye Institute (NEI) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NEI budget of $693,015,000 includes a decrease of $8,861,000 below the comparable FY 2012 level of $701,876,000. As the director of the NEI, it is my privilege to report on the many research opportunities that exist to reduce the burden of eye disease.

CLINICAL/TRANSLATIONAL RESEARCH

Gene Therapy: In 2008, NEI-supported investigators reported results from a landmark phase I clinical trial of gene therapy in three patients with a blinding, early onset retinal disease, Leber congenital amaurosis (LCA), which is caused by a defect of the *RPE65* gene. Treatment, consisting of injecting a viral vector to deliver normal copies of the *RPE65* gene, was well tolerated, and there was objective evidence of modest visual improvement in all three study subjects. To date, 15 participants have been treated and all have experienced visual improvements. Recently published clinical trial results find that increasing the dose with a second injection safely expands the area of retina exposed to the treatment (*RPE65*-AAV). Responsiveness of light-sensitive photoreceptor cells near injection sites increased after treatment. Younger participants, when compared to older participants, did not experience greater visual improvements. In fact, the two participants with the greatest visual acuity gains were among the oldest in the study. The researchers speculated that the number and health of remaining photoreceptors matter more than patient age, as the rate of photoreceptor loss varies considerably among people with *RPE65*-deficient LCA. The finding suggests that careful evaluation of photoreceptor cell health is important in determining potential clinical trial participants. Because safety was the primary outcome of this trial, a conservative approach was taken that limited treatment to the eye with poorer vision. In the future, the researchers plan to seek further visual gains by administering three injections of *RPE65*-AAV and treating the better eye.

A team of NEI investigators restored vision in a canine model of X-linked retinitis pigmentosa (XLRP) using a new gene therapy vector capable of transfecting both rod and cone cells. XLRP is a severe retinal disease that affects both rod and cone photoreceptor cells. Patients with XLRP experience night blindness as children and become blind by middle age. A common form of XLRP results from mutations in the *RPGR* gene. Treatment restored lost photoreceptor cell structure and repaired photoreceptor cell

connections to other retinal neurons that send visual signals to the brain. This study provides a clearer path to clinical trials for XLRP. In addition, gene therapy trials for age-related macular degeneration (AMD), choroideremia, Leber's hereditary optic neuropathy, Stargardt macular dystrophy (SMD), and Usher syndrome were launched this past year. Clinical trials for juvenile retinoschisis, achromatopsia, and retinitis pigmentosa are also planned. All of these trials were made possible by sustained NEI support to develop and refine gene therapy techniques.

Stem Cell Therapies: In January 2012 Advanced Cell Technologies published preliminary results of the first-ever clinical trials of a product derived from human embryonic stem cells (hESCs). These landmark clinical trials are evaluating hESC-derived retinal pigment epithelium (RPE) cells for the treatment of Stargardt's macular dystrophy (SMD) and age-related macular degeneration (AMD). In the two treated patients, there were no adverse events and both had modest but objective improvements in vision. The RPE is a highly specialized layer of cells adjoining the retina that support photoreceptor cell function. SMD and AMD are known to result from a diseased RPE.

GENETICS

NEI created the International AMD Genetics Consortium in 2010 to identify the remaining genetic risk variants for AMD. To increase the statistical power needed to identify genes that have small, yet significant contributions to AMD, the consortium is conducting a meta-analysis on 15 Genome Wide Association Studies (GWAS) representing over 8,000 patients with AMD and 50,000 controls. In addition to verifying known genes, the consortium identified 19 new gene variants. The genes identified in these studies function in the immune system, cholesterol transport and metabolism, and formation and maintenance of connective tissue. This study provides a nearly complete picture of genetic heritability for AMD. NEI's effort to unite the international research community to share GWAS data sets made it possible to solve a common goal in our understanding of this blinding disease.

In 2009, NEI established the NEI Glaucoma Human Genetics Collaboration (NEIGHBOR), a consortium of clinicians and geneticists at 12 institutions throughout the U.S. dedicated to identifying the genetics of glaucoma. NEIGHBOR collected and sequenced 6,000 DNA samples and is the largest genetics study of glaucoma. Thus far, NEIGHBOR investigators identified a risk variant in the gene CDKNB2. This gene is thought to play a role in the development of the optic nerve head, where retinal ganglion cell axons, which degenerate in glaucoma, converge to form the optic nerve. NEI will make GWAS data from NEIGHBOR available to the vision research community for further evaluation in 2012.

NEUROSCIENCE

In 2011, NEI awarded a grant to support *Project Prakash,* which combines an extraordinary scientific opportunity with a humanitarian mission. Understanding how the human brain learns to perceive objects remains a fundamental challenge in neuroscience.

Project Prakash seeks to treat older children born with congenital cataracts and other eye disorders and then study how their visual function develops. Visual development normally takes place during infancy before children acquire language and can communicate what they are seeing. By treating older children who can fully communicate, *Project Prakash* will permit scientists to more directly address the nature of neuroplasticity and visual development. This study will also provide important clinical insights to inform visual rehabilitation. India accounts for nearly 30 percent of the world's blindness. Many are poor children with treatable congenital eye disorders, but most never receive medical attention because they live in rural areas far from urban medical centers. Tragically, it is estimated that 60 percent of India's blind children die before reaching adulthood. *Project Prakash* is a unique opportunity to offer humanitarian medical aid while advancing the field of neuroscience.

Paul A. Sieving, M.D., Ph.D.
Director, National Eye Institute

Dr. Sieving became director of the National Eye Institute, NIH, in 2001. He came from the University of Michigan Medical School where he was the Paul R. Lichter Professor of Ophthalmic Genetics and the founding Director of the Center for Retinal and Macular Degeneration in the Department of Ophthalmology and Visual Sciences.

After undergraduate work in history and physics at Valparaiso University, Dr. Sieving studied nuclear physics at Yale Graduate School in 1970-73 under D. Allan Bromley and attended Yale Law School from 1973-74. He received his M.D. from the University of Illinois College of Medicine in 1978 and a Ph.D. in bioengineering from the University of Illinois Graduate College in 1981. Dr. Sieving completed an ophthalmology residency at the University of Illinois Eye and Ear Infirmary in Chicago. After post-doctoral study of retinal physiology with Roy H. Steinberg in 1982-83 at the University of California, San Francisco, he did a clinical fellowship in genetic retinal degenerations with Eliot Berson in 1984-85 at Harvard Medical School, Massachusetts Eye and Ear Infirmary.

Dr. Sieving is known internationally for studies of human progressive blinding genetic retinal neurodegenerations, including retinitis pigmentosa, and rodent models of these conditions. His laboratory study of pharmacological approaches to slowing degeneration in transgenic animal models led to the first human clinical trial of ciliary neurotrophic factor (CNTF) for retinitis pigmentosa, published in Proceedings of the National Academy of Sciences, 2006. He also developed a mouse model of X-linked retinoschisis and successfully treated this using gene therapy which restored retinal function. He maintains a clinical practice at NEI for patients with these and other genetic retinal diseases, including Stargardt juvenile macular degeneration.

Dr. Sieving served as Vice Chair for Clinical Research for the Foundation Fighting Blindness from 1996-2001. He is on the Bressler Vision Award committee and is a jury member for the €1 million annual 'Vision Award' of the Champalimaud Foundation, Portugal. He was elected to membership in the American Ophthalmological Society in 1993 and the Academia Ophthalmologica Internationalis in 2005. He received an honorary Doctor of Science from Valparaiso University in 2003 and has been named among the 'Best Doctors in America' multiple years. He has received numerous awards, including the Research to Prevent Blindness Senior Scientific Investigator Award, 1998; the Alcon Research Institute Award, 2000; and the Pisart Vision Award from the New York Lighthouse International for the Blind in 2005. Dr. Sieving was elected to the Institute of Medicine of the National Academy of Sciences in 2006.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director, National Institute of Environmental Health Sciences

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIEHS budget of $684,030,000 includes a decrease of $725,000 below the comparable FY 2012 level of $684,755,000.

INTRODUCTION

As the Dutch philosopher Desiderius Erasmus so succinctly put it: Prevention is better than cure. In most instances, disease is a result of a combination of age, genetics, and environment. But unlike age and genetics, environment is something that we can affect in order to prevent illness. As an environmental public health institute, the NIEHS is entrusted with the mission to prevent human suffering and illness by creating and sharing the knowledge necessary for understanding the role of the environment in disease, and thereby enable people to lead healthier lives. NIEHS continually strives to lead public health prevention efforts by providing research science and translation to inform decisions and policies at the individual, community, national, and global levels that prevent hazardous environmental exposures and thus reduce disease and disability. Many of the most challenging diseases—and most costly in terms of both human suffering and economic resources—are being shown to have strong environmental components. Diseases such as cardiovascular disease and stroke, that cause 1 in 3 deaths in America each year,[14] have been associated with exposure to environmental agents such as air pollution and second-hand smoke. An estimated nearly 70 percent of Americans over the age of 20 are overweight or obese; for children the figure is over 30 percent.[15] New research, including studies funded by the NIEHS, shows that obesity and its common companion diabetes are complex disorders that are affected not just by food consumption and physical exertion, but also by environmental factors including exposures to environmental contaminants during early life.[16] Greater understanding of the

[14] Roger Vl, et al. Heart disease and stroke statistics—2012 update: a report from the American Heart Association. Circulation. Dec.15, 2011:e12. Published online at: http://circ.ahajournals.org/content/early/2011/12/15/CIR/0b013e31823ac046.citation

[15] Roger Vl, et al. Heart disease and stroke statistics—2012 update: a report from the American Heart Association. Circulation. Dec.15, 2011:e14. Published online at: http://circ.ahajournals.org/content/early/2011/12/15/CIR/0b013e31823ac046.citation

[16] Janesick A, Blumberg B. Endocrine disrupting chemicals and the developmental programming of adipogenesis and obesity. Birth Defects Res C Embryo Today. Mar,93:34-50, 2011.

role of such exposures and concomitant efforts to prevent them could dramatically change the trend of this increasing public health epidemic. And the list goes on. Strong associations have been shown between exposure of pregnant mothers to chemicals, including polybrominated diphenyl ethers added to products as flame retardants, and a range of neurodevelopmental disorders, learning disabilities, and behavioral effects in their children.[17] NIEHS continues to commit significant efforts to increasing our understanding of these health effects and how they might be prevented. On a global level, the problem of respiratory illnesses resulting from exposure to indoor air pollution represents an area ripe for intervention. Toxic smoke from burning biofuels in cookstoves kills nearly 2 million people each year, largely women and children, according to the World Health Organization. NIEHS is part of the Global Alliance for Clean Cookstoves, a public-private initiative working to eliminate exposure to harmful cookstove smoke. This is a tractable prevention problem with a potentially huge payoff in public health.

NIEHS STRATEGIC PLANNING

Looking at this long list of environmentally related diseases raises the question, "How can one institute have an impact on research and disease prevention in all these areas?" To answer this question, NIEHS is striving to maximize its impact and leadership in the environmental health sciences through a comprehensive and inclusive strategic planning process focused on identifying key strategic goals for the next five years. Through this process, NIEHS hopes to achieve its vision of providing a catalyst for leading the field of environmental health sciences in applying state-of-the-art biomedical research to the most important issues surrounding environmental impacts on health.

Six broad-based themes of this plan have been established, through ongoing dialogue with research scientists and stakeholder groups. "Fundamental Research" investigates basic biological pathways of how our bodies function, to set the stage for asking more in-depth questions about the effects of the environment on biological systems. "Exposure Research" focuses on the study of environmental exposures themselves, internal and external to the body. And since NIEHS recognizes that information is only effective if it can be translated into sound decisions, "Translational Science" is identified as a key theme covering research that moves a basic science observation into a public health or medical application. NIEHS also affirms its commitment to "Health Disparities and Global Environmental Health" in recognition of the fact that individuals and communities that are socioeconomically disadvantaged also tend to suffer inequalities in both health and environmental burdens. Through "Training and Education," NIEHS recognizes the need to develop the next generation of top-notch, innovative, and dedicated environmental health scientists and professionals. Finally, to fulfill its mission and statutory mandate to disseminate information, NIEHS is committed to developing a full range of research translation and communication tools and creative

[17] Herbstman JD, et al. Prenatal exposure to PBDEs and neurodevelopment. Environ Health Perspect. 2010 May;118(5):712-9. Epub 2010 Jan 4.

stakeholder partnerships. This "Communications and Engagement" theme is vital for realizing the institute's mission to promote public health and prevent environmentally related disease and disability. Two crosscutting themes, "Collaborative and Integrative Approaches" and "Knowledge Management" will be implemented across the other themes to ensure the success of the goals throughout the strategic plan.

RECENT ACCOMPLISHMENTS

The NIEHS strategic plan highlights areas of leadership that will build on an impressive list of recent research accomplishments. For example, NIEHS-funded researchers recently published the first study documenting how exposure to perfluorinated compounds (PFCs), widely used in manufactured products such as non-stick cookware, was associated with lowered immune response to vaccinations in children.[18] Other recent research funded by NIEHS has shown that even moderate air pollution, at levels generally considered safe under current federal regulations, increases the risk of stroke by 34 percent.[19]

NIEHS is also committed to helping those impacted by environmental exposures. In the aftermath of the Deepwater Horizon disaster, many questions remain about the long-term impact on the health of Gulf Coast residents and communities. NIEHS is leading a trans-NIH effort to create a network of community and university partnerships that seeks to identify personal and community health effects stemming from the Deepwater Horizon oil spill and to enhance community resiliency to potential disasters. The five-year, $25.2 million program will support population-based and laboratory research, which will ultimately develop the scientific evidence base needed to promote health and well-being for people living along the Gulf Coast who are at greatest risk for potential adverse physical, psychological, and behavioral health effects. In addition, research will seek to develop new strategies to enhance capacity to respond to future disasters and prevent or minimize adverse health effects arising from them. Once completed, research findings from the Deepwater Horizon Research Consortia should contribute to the evidence base needed to improve preparedness and response aimed at minimizing disaster-related health impacts.

Ultimately, NIEHS remains committed to its overall mission to discover how the environment affects people's health, in order to promote healthier lives.

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[18] Grandjean P, Wreford Anderson E, Budtz-Jorgensen E, Nielson F, Molbak K, Weihe P, Heilman C. Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. *JAMA*. 2012; 307:391-397. Doi:10.1001/jama.2011.2034.

[19] Gregory A, et al. Ambient air pollution and the risk of acute ischemic stroke. *Arch Intern Med.* 2012;172(3):229-234.

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director, National Institute of Environmental Health Sciences

Linda S. Birnbaum, Ph.D., is the director of the National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health, and the National Toxicology Program (NTP). As NIEHS and NTP director, Birnbaum funds biomedical research to discover how the environment influences human health and disease. The Institute also supports training, education, technology transfer, and community outreach.

A board certified toxicologist, Birnbaum has served as a federal scientist for 31 years. Prior to her appointment as NIEHS and NTP director, she spent 19 years at the Environmental Protection Agency where she directed the largest division focusing on environmental health research. Birnbaum started her federal career with 10 years at the NIEHS — first as a senior staff fellow in the National Toxicology Program, then as a principal investigator and research microbiologist, and finally as a group leader for the Institute's Chemical Disposition Group.

Birnbaum has received many awards and recognitions. In October 2010, she was elected to the Institute of Medicine of the National Academies, one of the highest honors in the fields of medicine and health. She was elected to the Collegium Ramazzini, and received an honorary Doctor of Science from the University of Rochester and Distinguished Alumna Award from the University of Illinois. Her awards include the Women in Toxicology Elsevier Mentoring Award, the Society of Toxicology Public Communications Award, EPA's Health Science Achievement Award and Diversity Leadership Award, and 12 Science and Technology Achievement Awards, which reflect the recommendations of EPA's external Science Advisory Board for specific publications. Birnbaum is also an active member of the scientific community. She was vice president of the International Union of Toxicology, the umbrella organization for toxicology societies in more than 50 countries; former president of the Society of Toxicology, the largest professional organization of toxicologists in the world; former chair of the Division of Toxicology at the American Society of Pharmacology and Therapeutics; and former vice president of the American Aging Association.

She is the author of more than 700 peer-reviewed publications, book chapters, abstracts, and reports. Birnbaum's own research focuses on the pharmacokinetic behavior of environmental chemicals, mechanisms of action of toxicants including endocrine disruptors, and linking of real-world exposures to health effects. She is also an adjunct professor in the Gillings School of Global Public Health, the Curriculum in Toxicology, and the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill, as well as in the Integrated Toxicology Program at Duke University. A native of New Jersey, Birnbaum received her M.S. and Ph.D. in microbiology from the University of Illinois at Urbana-Champaign.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Richard J. Hodes, M.D.
Director, National Institute on Aging

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute on Aging (NIA) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIA budget includes $1,102,650,000, which is $522,000 over the comparable FY 2012 level of $1,102,128,000.

Over 40 million people age 65 and older live in the United States, and data from the Federal Interagency Forum on Aging-Related Statistics indicate that their numbers will double by 2040. In less than 50 years, the number of "oldest old" – people ages 85 and older – may quadruple. As record numbers of Americans reach retirement age and beyond, profound changes will occur in our economic, health care, and social systems.

The NIA leads the national effort to understand aging and to identify and develop interventions that will help older adults enjoy robust health and independence, remain physically active, and continue to make positive contributions to their families and communities. We support genetic, biological, clinical, behavioral, and social research related to the aging process, healthy aging, and diseases and conditions that often increase with age. We also carry out the crucial task of training the next generation of researchers who specialize in understanding and addressing the issues of aging and old age.

BUILDING MOMENTUM IN THE FIGHT AGAINST ALZHEIMER'S DISEASE

Estimates of how many people in the United States currently have Alzheimer's disease (AD) range from 2.7 million to 5.1 million, depending on how AD dementia is defined and measured. However, scientists agree that unless the disease can be effectively treated or prevented, the numbers will increase significantly if current population trends continue.

At the same time, there has never been greater cause for optimism. In recent years, we have expanded our understanding of how the disease takes hold and progresses, identified promising targets for intervention, and developed new models to speed discovery. For example, researchers have developed a mouse model that expresses human tau, one of AD's pathological hallmarks, and discovered that tau pathology is transmitted from cell to cell, beginning in the brain's entorhinal cortex and spreading from one brain region to the next. This discovery provides insight into AD's earliest

development and offers a model for testing mechanisms and functional outcomes associated with disease progression. In another study, investigators "reprogrammed" human skin cells into induced pluripotent stem cells, which then differentiated into working neurons; this breakthrough will facilitate the study of AD in human neurons and provide important insight into the etiology of the disease.

Advances in imaging technology, most notably through the NIH-supported Alzheimer's Disease Neuroimaging Initiative (ADNI), have expanded our ability to understand the underlying pathology of AD, diagnose the disease, track the progress of interventions, and even identify individuals at risk. ADNI data were also used last year to develop new, more comprehensive diagnostic guidelines at both the clinical and pathological levels.

NIH currently supports over 35 clinical trials, including both pilot and large scale trials, of a wide range of interventions to prevent, slow, or treat AD and/or cognitive decline; over 40 compounds are in preclinical development through the AD Translational Initiative. NIA also participates in the NIH Neuroscience Blueprint under which investigators developing new compounds will have access to drug development services not typically available to the academic research community.

Investigators are also "re-purposing" treatments for other diseases as treatments for AD, with encouraging results. For example, a pilot clinical trial recently demonstrated that a nasal-spray form of insulin was able to delay memory loss and preserve cognition in people with cognitive deficits ranging from mild cognitive impairment (often a precursor condition to AD) to moderate AD. In a separate study, the skin cancer drug Bexarotene promoted clearance of amyloid-beta and reversed cognitive deficits in mice. These preliminary findings offer new and exciting possibilities for the effective prevention and treatment of AD.

NIA has been an active participant in the implementation of the National Alzheimer's Project Act, including the development of a National Plan to Address Alzheimer's Disease. A new presidential initiative to boost support for AD research, which will provide an additional $50 million in FY 2012 and $80 million in FY 2013 for the disease, will stimulate and support important groundbreaking work in a number of areas, including AD extensive whole genome sequencing to identify genetic risk and protective factors for AD. Our activities will be informed by input from expert advisors participating in the May 2012 Alzheimer's Disease Research Summit.

UNDERSTANDING AGING AT THE MOST BASIC LEVEL

NIA initiatives on the molecular mechanisms of aging, from in-depth study of single cells to the broad study of organisms at the systems level, continue to advance our understanding of the basic underpinnings of the aging process. For example, investigators recently found that it was possible to delay onset of age-related changes in the skeletal muscle, fat, and eye tissues in mice by removing senescent cells – i.e., cells that are alive but no longer functional. The study also found a slowing of progression of

age-related disorders in the mice. These results suggest that cell senescence may be a fundamental mechanism that drives aging.

IMPROVING THE HEALTH AND WELL-BEING OF OLDER AMERICANS

As the American population continues to age, it is imperative that we identify the optimal means to address the unique health needs of older individuals. For example, the Centers for Disease Control and Prevention reports that fully half of older Americans have at least two chronic health conditions that compromise quality of life. NIA is participating in a trans-NIH initiative to develop interventions to modify behavior and improve health outcomes among individuals with three or more chronic conditions.

Increased adherence to recommended medication regimens promises substantial improvements in public health as well as savings in healthcare costs. NIA-supported investigators found that simply encouraging people to write down the time and date when they plan to receive a flu vaccination can significantly increase vaccination rates. NIA also participates in an NIH-wide initiative to identify practical interventions to improve medication adherence in the primary care setting.

Studies have shown that regular physical activity can improve physical performance in older people, but definitive evidence that physical activity can prevent mobility disability is lacking. The NIA supports the Lifestyle Interventions and Independence for Elders Study to assess the effects of a structured physical activity program in 1,600 sedentary older individuals. With the U.S. Surgeon General, the NIA has also launched its nationwide *Go4Life* campaign to motivate older Americans to engage in physical activity and exercise.

In the past year, preliminary results were released from the "Oregon Lottery" study, in which randomly-selected low-income Oregon residents were able to enroll in the state's Medicaid program. Compared to a control group, the new Medicaid enrollees reported improved health and well-being, as well as reduced financial strain. Use of important types of health care services such as preventive care also increased.

EMPOWERING THE NEXT GENERATION OF AGING RESEARCHERS

The need for health care professionals who specialize in the unique needs of older individuals is becoming ever more urgent. We must not only increase the number of practicing physicians trained in geriatrics and in subspecialty fields related to the health problems of elders, but also foster the development of the next generation of physician-scientists whose clinical research will lead to improved care and more effective treatment options for older patients with complex medical conditions. Recently, NIA established the Grants for Early Medical/Surgical Subspecialists' Transition to Aging Research (GEMSSTAR) program to promote future leaders in clinical aging research through support of physicians who seek to become clinician-scientists in geriatric aspects of their subspecialty. NIA has also established a program targeting undergraduate students from diverse backgrounds in order to advance their interest in and knowledge of aging issues.

Richard J. Hodes, M.D.
Director, National Institute on Aging

Richard J. Hodes, M.D., directs the research program of the National Institute on Aging (NIA) at the National Institutes of Health. A leading immunologist, Dr. Hodes was named Director of the NIA in 1993, to oversee studies of the basic, clinical, epidemiological and social aspects of aging.

Under Dr. Hodes' stewardship, the NIA budget has surpassed $1 billion, reflecting increased public interest in aging as America and the world grows older. Dr. Hodes has devoted his tenure to the development of a strong, diverse, and balanced research program, focusing on the genetics and biology of aging, basic and clinical studies aimed at reducing disease and disability, including Alzheimer's disease and age-related cognitive change, and investigation of the behavioral and social aspects of aging. Ultimately, these efforts have one goal -- improving the health and quality of life for older people and their families.

In the past decade, the NIA has worked in new and innovative ways to conduct research and to translate research findings into practical interventions and public information. In biology, research conducted and supported by the NIA examines the genetic and other factors influencing lifespan and age related diseases and conditions. Research in geriatrics is uncovering new ways to combat frailty with age, and social and demographic research is deepening understanding of the individual behaviors and societal decisions that affect well-being. In Alzheimer's disease (AD), new initiatives to find genes involved in AD and to identify biomarkers are expected to considerably reduce the length and cost of clinical trials, thereby speeding up the testing of new therapies for AD.

Dr. Hodes is a graduate of Yale University and received his M.D., from Harvard Medical School. He completed training in Internal Medicine at Massachusetts General Hospital and in Oncology at the National Cancer Institute. Dr. Hodes is a Diplomate of the American Board of Internal Medicine. In 1995, he was elected as a member of The Dana Alliance for Brain Initiatives; in 1997, he was elected as a Fellow of the American Association for the Advancement of Science; and in 1999, he was elected to membership in the Institute of Medicine of the National Academy of Sciences.

Dr. Hodes' research laboratory in the National Cancer Institute focuses on the cellular and molecular mechanisms that regulate the immune response, with major fields of current emphasis in: 1) the function of costimulation in T and B cell lineage development and function, and 2) regulation of telomere length, and its functional consequences, in both human and mouse model systems. Additional background is available at the lab's website, http://ccr.cancer.gov/Staff/Staff.asp?StaffID=472.

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIAMS budget of $535,610,000 includes an increase of $462,000 over the comparable FY 2012 level of $535,148,000.

INTRODUCTION

As the primary Federal agency for supporting medical research on diseases of the bones, joints, muscles, and skin, NIAMS touches the lives of nearly every American. Training the basic and clinical scientists who carry out this research, and disseminating information on research progress in these diseases, are two other important components of the NIAMS mission.

USING SCIENCE TO INFORM HEALTH CARE DECISIONS

Over the past two decades, the NIH Study of Osteoporotic Fractures (SOF) has provided information that health care providers are using to assess people's bone health. SOF's finding that bone mineral density (BMD) relates closely to fracture risk, for example, contributed to Medicare's decision to pay for numerous people to get their BMD measured every two years. Many started taking bone-preserving drugs because of their results, and the rate of hip fractures dropped nearly 25 percent among female beneficiaries[20]. New, longer-term data from SOF could refine the screening guidance: women at the highest risk of osteoporosis might benefit from annual exams, while frequent measurements may be unnecessary for others. In fact, women with the lowest risk could be tested much less frequently unless other aspects of their health change.

As multiple treatments become available for various conditions, research is needed to help clinicians decide which options are best for their patients. Studies of adults who have rheumatoid arthritis (RA) suggest that aggressive treatment is more beneficial than waiting until the disease progresses. A group of rheumatologists tested whether a similar approach would reduce the disability and health care costs of juvenile idiopathic arthritis (JIA). They compared two therapies and determined that early treatment with either strategy increased the likelihood that the joint-destroying processes would stop.

Many diseases within the NIAMS mission involve pain, fatigue, and other difficult-to-measure symptoms. The ability to quantify changes in these parameters could enhance clinical outcomes research and, ultimately, clinical practice. NIAMS is one of several NIH components engaged in the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative to develop such a tool. In addition to managing PROMIS on behalf of NIH, NIAMS is encouraging researchers to use the resource in ongoing clinical studies of rheumatic, musculoskeletal, and skin diseases.

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[20] Brauer CA, et al. JAMA. 2009. PMID: 19826027

For the past decade, researchers have been monitoring the health of people who have low back pain due to intervertebral disk herniation, lumbar spinal stenosis, or degenerative spondylolisthesis. Early findings showed that, in general, most surgical patients fared better than patients who received non-operative care, although many patients got better without surgery. Recent data show that the cost-effectiveness of surgery for low back pain due to these disorders—four years after an operation—is comparable to that of other common treatments for non-musculoskeletal conditions.

Community engagement is a key component for translating interventions into health care and integrating lifestyle changes into daily living. To address the well-documented disparities in medical knowledge and research participation, NIAMS will continue its Multicultural Outreach Initiative to improve access to health information for underserved minority populations. FY 2013 plans include field testing program materials and creating an electronic toolkit to facilitate their dissemination.

INVESTING IN BASIC RESEARCH

Itch is an often difficult and sometimes debilitating symptom of many skin diseases and other disorders within the NIAMS mission. Poor knowledge of the mechanisms underlying chronic itch has hampered the development of pharmacologic treatments. In FY 2013, NIAMS will encourage basic and translational studies in this area.

NIAMS maintains a considerable investment into the genetic and cellular basis of osteoarthritis (OA), with the goal of identifying potential targets for therapies that halt tissue degeneration. Even after researchers develop treatments to stop or reverse OA progression, however, some patients will require total joint replacement. With support from the American Recovery and Reinvestment Act of 2009, researchers made a surprising discovery about the lubricating layer that forms around metal-on-metal hip implants. Instead of cell-based fluid made by the patient, the lubricant is a synthetic material produced through friction. This finding could lead to longer-lasting materials which, in turn, could improve the surgeries' success and reduce their long-term costs.

With the advent of new laboratory and data mining tools, investigators are making connections among biologic processes and organ systems that previously were viewed independently. For example, researchers are learning that inflammation, which plays an important role in RA and other autoimmune joint diseases, is involved in OA onset and osteoarthritic joint degeneration. Others are exploring how normally harmless microorganisms can lead to RA by causing the immune system to attack healthy tissue.

The technologic advances related to genome-wide analyses have enabled investigators to identify a genetic mutation that causes a rare childhood disease characterized predominantly by inflammation and fat loss. The disorder, named chronic atypical neutrophilic dermatosis with lipodystrophy and elevated temperature (CANDLE), may actually represent a spectrum of diseases that have been described in

the literature under a variety of names. More importantly, since no treatment for this disease exists, the findings may have uncovered a possible target for future therapies.

ADVANCING TRANSLATIONAL SCIENCES

NIAMS supports several large programs to encourage teams of translational researchers. In FY 2013, it again will partner with other NIH institutes to fund applications for the Wellstone Muscular Dystrophy Cooperative Research Centers program. The Centers have facilitated numerous basic discoveries and animal tests since their establishment in 2003. A group of investigators that includes Wellstone researchers recently published preclinical data about small molecules that target the defective RNA that causes myotonic dystrophy type 1. The cell-culture and mouse-model findings have the potential to benefit people who have myotonic dystrophy type 1; their promise also extends to other conditions that might be amenable to RNA-targeted therapies.

NIAMS strengthened its Small Business Innovation Research (SBIR) program in recent years by inviting eligible companies to propose studies on specific topics that complement the Institute's other grants. Results from the targeted efforts include a cell-derived human skin substitute for use in consumer product testing, drug discovery, and toxicity screening. NIAMS will continue to look for opportunities that could benefit from an SBIR focus and will solicit applications as areas are identified.

CONCLUSION

The advances described above are just a few of the contributions that NIAMS-funded investigators have made to save and improve millions of American lives. Collectively, the Institute's research, training, and health information programs have significantly advanced our understanding of how to treat or prevent many common, chronic, costly diseases. Looking forward, this progress will serve as a strong foundation for the future, as the burden that these conditions place on individuals and society is reduced and, over time, eliminated.

Stephen I. Katz, M.D., Ph.D.
Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases

Stephen I. Katz, M.D., Ph.D. has been Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases since August 1995 and is also a Senior Investigator in the Dermatology Branch of the National Cancer Institute. He was born in New York in 1941. His early years were spent in the Washington, D.C., and Bethesda, Maryland areas. After attending the University of Maryland, where he graduated with honors, he graduated from the Tulane University Medical School with honors in 1966. He completed a medical internship at Los Angeles County Hospital and did his dermatology residency at the University of Miami Medical Center from 1967 to 1970. He served in the U.S. military at Walter Reed Army Medical Center from 1970 to 1972. From 1972 to1974, Dr. Katz did a postdoctoral fellowship at the Royal College of Surgeons of England and obtained a Ph.D. degree in immunology from the University of London in 1974. He then became Senior Investigator in the Dermatology Branch of the National Cancer Institute and assumed the position of Acting Chief in 1977, and then Chief in 1980, a position he held until 2001. In 1989, Dr. Katz also assumed the position of Marion B. Sulzberger Professor of Dermatology at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, a position from which he resigned in 1995.

Dr. Katz has focused his studies on immunology and the skin. His research has demonstrated that skin is an important component of the immune system both in its normal function and as a target in immunologically-mediated disease. In addition to studying Langerhans cells and epidermally-derived cytokines, Dr. Katz and his colleagues have added considerable new knowledge about inherited and acquired blistering skin diseases.

Dr. Katz has trained a large number of outstanding immunodermatologists in the U.S., Japan, Korea, and Europe. Many of these individuals are now leading their own high-quality, independent research programs. He has served many professional societies in leadership positions including as a member of the Board of Directors and President of the Society for Investigative Dermatology, on the Board of the Association of Professors of Dermatology, as Secretary-General of the 18th World Congress of Dermatology in New York in 1992, as Secretary-Treasurer of the Clinical Immunology Society, and as President of both the International League of Dermatological Societies and the International Committee of Dermatology. Dr. Katz has also served on the editorial boards of a number of clinical and investigative dermatology journals, as well as several immunology journals. He has received many honors and awards, including the Master Dermatologist Award and the Sulzberger Lecture Award of the American Academy of Dermatology, the National Cancer Institute's Outstanding Mentor Award, the Harvey J. Bullock, Jr., EEO Award in recognition of his extraordinary leadership in scientific, programmatic, and administrative arenas, the Excellence in Leadership Award from the Intl. Pemphigus Foundation, the "Change It" Champion Award from Parent Project Muscular Dystrophy, honorary membership in numerous international dermatological societies, and election into the Institute of Medicine of the National Academy of Sciences (USA). He has also received the Alfred Marchionini Gold Medal, the Lifetime

Achievement Award of the American Skin Association, Doctor Honoris Causa Degrees from Semmelweis University in Budapest, Hungary, Ludwig Maximilian University in Munich, Germany, and the University of Athens in Greece. He also received the Rothman Award for distinguished service to investigative cutaneous medicine and the Kligman/Frost Award, both from the Society for Investigative Dermatology. Dr. Katz has twice received the Meritorious Rank Award and has also received the Distinguished Executive Presidential Rank Award, the highest honor that can be bestowed upon a civil servant.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

James F. Battey, Jr., M.D., Ph.D.
Director, National Institute on Deafness and Other Communication Disorders

Mr. Chairman and Members of the Subcommittee:

I am pleased to present the President's budget request for the National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIDCD budget of $417,297,000 includes an increase of $1,519,000 over the comparable FY 2012 level of $415,778,000.

The NIDCD conducts and supports research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. Our Institute focuses on disorders that affect the quality of life of millions of Americans in their homes, workplaces, and communities. The physical, emotional, and economic impact for individuals living with these disorders is tremendous. NIDCD continues to make investments to improve our understanding of the underlying causes of communication disorders, as well as their treatment and prevention. It is a time of extraordinary promise, and I am excited to be able to share with you some of NIDCD's ongoing research and planned activities addressing communication disorders.

EARLY EXPERIENCE SHAPES SALT PREFERENCE

Even though we know that too much salt is bad for our health, many of us still consume too much of it. In a typical diet, a lot of salt comes from starchy foods, such as breads and cereals. Too much salt can cause high blood pressure, or hypertension. Although hypertension itself usually has no symptoms, it can cause serious health problems such as stroke, heart failure, heart attack and kidney failure. NIDCD-supported scientists determined that babies whose diets contain starchy, salty foods will develop a preference for salty taste by as early as six months of age, as compared to babies who have not been given salty foods. During a preference test, the babies accustomed to saltier diets consumed 55 percent more salt than their unexposed peers. Salt preference endures into the preschool years, when children exposed to a salty diet as babies are more likely to consume plain salt. This research identifies a potential role for early dietary experiences in shaping taste preferences that could influence salt consumption in our adult years. If these results can be repeated in a larger study population, it suggests that we may be able to reduce salt consumption in future generations by encouraging parents to restrict salt in their babies' early diets. Reducing salt consumption will also reduce the incidence of hypertension, thus reducing healthcare costs due to hypertension and the serious health problems it can cause.

IDENTIFICATION OF MAJOR PROTEINS INVOLVED IN HEARING

According to NIDCD statistics, two to three out of 1,000 children in the U.S. are born deaf or hard of hearing, with changes in genes being a major cause of hearing impairment. NIDCD-supported scientists have shown that mutations in the TMC1 and TMC2 genes cause hereditary deafness in humans and mice. Further, they discovered that the proteins encoded by TMC1 and TMC2 genes may be key components of the long-sought after mechanotransduction channel in the inner ear—the place where mechanical stimulation of sound waves is transformed into electrical signals recognized by the brain as sound. Using mice without the TMC1 and TMC2 genes, the scientists discovered the mice had a deficit in the mechanotransduction channels in their sterocilia, the sound-sensing organelles of the inner ear, while the rest of the auditory hair cell's structure and function was normal. These genes and the proteins they regulate are the strongest candidates yet in the search for the transduction channel. If these genes do indeed encode the transduction channel, they will be useful tools to screen for drugs or molecules that bind to or pass through the channel and could be used to prevent damage to hair cells.

KEEP NOISE DOWN ON THE FARM

Farming is loud work. Squealing pigs, grinding combines, whirring power tools, and roaring vehicles can add up to a lot of noise. Prevention and treatment of noise induced hearing loss (NIHL) is a priority for the NIDCD. NIDCD's campaign "It's a Noisy Planet. Protect their Hearing" promotes early education of elementary and middle-school children about NIHL and how to prevent it. The NIDCD has introduced new materials for parents of children who live and work on a farm to help them develop healthy hearing habits and protect their hearing for life. The NIDCD hopes that these materials will help protect individuals who live and work on a farm from developing NIHL. Preventing NIHL will improve quality of life for the millions exposed to noise, and decrease overall healthcare costs.

SALIVA IS EFFECTIVE IN SCREENING FOR CMV INFECTION IN NEWBORNS

In June, NIDCD-supported scientists reported that swabbing a newborn's mouth for saliva can be used to quickly and effectively screen for cytomegalovirus (CMV) infection, a leading cause of progressive hearing loss in children. Scientists at the University of Alabama at Birmingham (UAB) determined that saliva correctly identified every baby born with the infection when liquid samples were used, and 97.4 percent of babies when the samples were dried. Most babies infected with CMV don't show symptoms at birth. NIDCD has placed a high priority on developing diagnostic tools to screen babies for congenital CMV infection, so that those who test positive can be monitored for possible hearing loss. These children can be provided with appropriate intervention as soon as possible. Because of this research, we know that testing saliva is an effective way to identify children at risk for hearing loss due to CMV.

HIV-EXPOSED CHILDREN AT HIGH RISK OF LANGUAGE DELAY

Children who do not use language well may not do well in school and may also have difficulty communicating with their peers and establishing friendships. A recent study funded by the NIDCD and seven other NIH Institutes found that 35 percent of a group of school-age children born to women with an HIV infection during pregnancy have difficulty understanding spoken words and expressing themselves verbally. These data should encourage those caring for children exposed to HIV in the womb to provide early treatment for language impairments.

James F. Battey, Jr., M.D., Ph.D.
Director, National Institute on Deafness and Other Communication Disorders

James F. Battey, Jr., received his Bachelor of Science degree in physics from the California Institute of Technology in 1974. He received an M.D. and Ph.D. in biophysics from Stanford University School of Medicine in 1980. After receiving training in pediatrics, he pursued a postdoctoral fellowship in genetics at Harvard Medical School under the mentorship of Dr. Philip Leder. Since completing his postdoctoral fellowship in 1983, he has held a variety of positions at the National Institutes of Health, serving in the National Cancer Institute, National Institute of Neurological Disorders and Stroke, and the National Institute on Deafness and Other Communication Disorders (NIDCD). Currently, he is the director of the NIDCD, and also serves as the vice chair of the NIH Stem Cell Task Force. He has been married for 31 years to Frances Battey, and has two sons, Michael and JJ.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Patricia A. Grady, Ph.D., RN, FAAN
Director, National Institute of Nursing Research

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Nursing Research (NINR) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NINR budget of $144,153,000, includes a decrease of $444,000 below the comparable FY 2012 level of $144,597,000.

INTRODUCTION

I appreciate the opportunity to share with you a brief summary of some of the recent activities and future scientific directions of NINR. NINR supports clinical and basic research to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, enhance palliative and end-of-life care, and train the next generation of scientists. In doing so, NINR promotes and improves the health of individuals, families, and communities across the lifespan, in a variety of clinical settings and within diverse populations. NINR's emphasis on clinical research and training places NINR in a position to make major contributions to developing the evidence base for science-driven practice through innovative treatment and behavioral research.

Over the past year, we have commemorated NINR's 25th anniversary at NIH through a series of scientific outreach events that culminated in October 2011 with the release of NINR's new Strategic Plan: *Bringing Science to Life*. As NINR looks ahead to the next 25 years, the Institute is well-positioned to continue to advance rigorous science, develop and support evidence-based science-driven interventions across the lifespan, develop future leaders in nursing science, and contribute to improving the Nation's health and national health care system.

ADVANCING THE QUALITY OF LIFE: SYMPTOM MANAGEMENT

With the aging of a major sector of the Nation and advances in treatment of formerly fatal diseases, we are faced with a population that is living with multiple chronic conditions. The challenge of treating and managing these multiple conditions and their associated symptoms is one that confronts nearly all health practitioners, especially nurses involved with chronic illness management. NINR has invested deeply in the area of symptom management, from funding basic research on pain in our Intramural Research Program (IRP) to our extramural support for psychosocial and nutritional

interventions to improve symptoms of chronic heart failure. Further, recognizing that chronic illness strikes across the lifespan, NINR also supports research aimed at helping children and adolescents manage their own chronic conditions and their symptoms more effectively to improve their quality of life. Finally, NINR initiated a call for research on the interconnections of diabetes and asthma, both on the rise in the U.S.; this research is focused on early life exposures that are associated with both conditions, as well as interventions that target the management of each disease and their synergisms.

HEALTH PROMOTION AND DISEASE PREVENTION

NINR is also heavily committed to health promotion and disease prevention. Nurses are often in unique positions as the health providers with the most frequent interactions with individuals and their support networks, and are therefore well-poised to help develop interventions that promote health and prevent disease. In one example, NINR currently supports an innovative community-based program in urban Pennsylvania that trains male Latino lay health advisors who provide their peers information on community support resources, including health care resources. NINR also is leading a funding opportunity focused on developing healthy habits in children and adolescents that lead to lifelong sustainable healthy behaviors that prevent disease and disability. Finally, in line with our focus on health promotion and disease prevention across the lifespan, NINR supported a research project that developed a successful program to guide mothers of very preterm infants in correctly feeding their vulnerable infants.

INVESTING IN NURSE SCIENTISTS

NINR is strongly committed to the development of future health scientists, with a specific focus on the training of nurse scientists. Along with extramural research grants and fellowships that support pre- and post-doctoral students and junior and senior researchers, NINR offers a number of intramural training opportunities to develop nurse scientists. This year, we are proud to once again offer the NINR Summer Genetics Institute, a month-long, intensive course in genetics for nurse scientists at all career levels. The course is designed to increase research in genetics among graduate students and faculty in nursing, and expand the knowledge base among clinicians for genetics in clinical practice. NINR also sponsors the Methodologies Boot Camp, a one-week intensive research training course at NIH that focuses on applying state-of-the-art methodologies to studies of symptom management, including pain, fatigue, and sleep.

END OF LIFE AND PALLIATIVE CARE

With advances in treatment for chronic diseases and the aging of our population, we as a society are facing new challenges in understanding the complexities of decision-making issues surrounding palliative and end-of-life care for those with advanced illness. As the lead NIH Institute for end-of-life research, NINR is committed to supporting research that leads to science-driven practices in palliative care that assists individuals, families, caregivers, and health care professionals in alleviating symptoms and planning for end-of-life decisions. In August 2011, NINR convened a three-day National Summit

on, "The Science of Compassion: Future Directions in End-of-Life and Palliative Care". The Summit, co-sponsored by partners across NIH, examined the state of research and clinical practice in end-of-life and palliative care and, with almost 1,000 registrants, provided an opportunity for scientists, health care professionals, and public advocates to come together to catalyze and shape the future research agenda for this critical scientific area. NINR also supports, along with the NIH OD, a palliative care research cooperative to develop an enhanced evidence base for palliative care by facilitating multi-site research studies and clinical trials.

INVESTING IN INNOVATION

NINR supports innovations that advance patient care, help lower the cost of health care, and take advantage of the advances in real-time personalized information on patients that guide health care today. For example, NINR supported two critical phases of the development of a novel "lab-on-a-chip" device for rapidly detecting HIV. The technique has proved highly successful, and the research team has gone on to refine and clinically test this microfluid-based lab-on-a-chip – or mCHIP – in real life settings, with studies demonstrating that the mCHIP can accurately, rapidly, and cost-effectively detect clinically relevant infectious diseases in resource-limited settings. Other NINR-supported researchers have developed a novel, automated medication dispenser that reminds patients when to take medication, monitors dosage, and reduces treatment errors. The new dispenser will be the first on the market that can deliver not only all common forms of drugs but also biologically-derived injectables.

CONCLUSION

Nursing science has a central role in developing the evidence-base for science-driven practices in health care. NINR's research agenda has guided and will continue to guide the advances in this field of health research through the implementation of our new Strategic Plan. NINR looks forward to continuing its support of innovative nursing science focused on some of the most important health and healthcare related issues of today.

Patricia A. Grady, Ph.D., RN, FAAN
Director, National Institute of Nursing Research

Dr. Patricia A. Grady was appointed Director of National Institute of Nursing Research, on April 3, 1995. She earned her undergraduate degree in nursing from Georgetown University in Washington, DC. She pursued her graduate education at the University of Maryland, receiving a master's degree from the School of Nursing and a doctorate in physiology from the School of Medicine.

An internationally recognized researcher, Dr. Grady's scientific focus has primarily been in stroke, with emphasis on arterial stenosis and cerebral ischemia. She was elected to the Institute of Medicine in 1999 and is a member of several scientific organizations, including the Society for Neuroscience, the American Academy of Nursing, and the American Neurological Association. She is also a fellow of the American Heart Association Stroke Council.

In 1988, Dr. Grady joined NIH as an extramural research program administrator in the National Institute of Neurological Disorders and Stroke (NINDS) in the areas of stroke and brain imaging. Two years later, she served on the NIH Task Force for Medical Rehabilitation Research, which established the first long-range research agenda for the field of medical rehabilitation research. In 1992, she assumed the responsibilities of NINDS Assistant Director. From 1993 to 1995, she was Deputy Director and Acting Director of NINDS. Dr. Grady served as a charter member of the NIH Warren Grant Magnuson Clinical Center Board of Governors.

Before coming to NIH, Dr. Grady held several academic positions and served concurrently on the faculties of the University of Maryland School of Medicine and School of Nursing. Dr. Grady has authored or co-authored numerous articles and papers on hypertension, cerebrovascular permeability, vascular stress, and cerebral edema. She is an editorial board member of the major stroke journals. Dr. Grady lectures and speaks on a wide range of topics, including future directions in nursing research, developments in the neurological sciences, and Federal research opportunities.

Dr. Grady has been recognized with several prestigious honors and awards for her leadership and scientific accomplishments, including the first award of the Centennial Achievement Medal from Georgetown University School of Nursing and Health Sciences, being named the inaugural Rozella M. Schlotfeld distinguished lecturer at the Frances Payne Bolton School of Nursing at Case Western Reserve University, and receiving the honorary degree of Doctor of Public Service from the University of Maryland. Dr. Grady was named the Excellence in Nursing Lecturer by the Council on Cardiovascular Nurses of the American Heart Association. In 2005, Dr. Grady received Doctor of Science, Honoris Causa degrees from the Medical University of South Carolina and Thomas Jefferson University, and Columbia University School of Nursing honored her with its prestigious Second Century Award for Excellence in Health Care. In 2008, Dr. Grady received a Doctor of Science, Honoris Causa degree from the State University of New York Downstate Medical Center. Dr. Grady is a past recipient of the NIH Merit

Award and received the Public Health Service Superior Service Award for her exceptional leadership.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Kenneth R. Warren, Ph.D.
Acting Director, National Institute on Alcohol Abuse and Alcoholism

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIAAA budget of $457,104,000 reflects a decrease of $1,868,000 below the comparable FY 2012 level of $458,972,000 million.

SCOPE OF THE PROBLEM

The Centers for Disease Control and Prevention (CDC) ranks alcohol as the third leading cause of preventable death in the United States (U.S.), and the World Health Organization (WHO) lists alcohol as one of the top ten causes of Disability Adjusted Life Years (DALYs) in the U.S. And, according to a new study by the CDC, the cost of excessive alcohol consumption in the U.S. reached $223.5 billion in 2006.

On a more personal level, I would venture that each of you knows someone who has experienced an alcohol-related problem. It could be a child who has difficulty in school as a result of prenatal alcohol exposure. Perhaps you have a relative or colleague who is one of the almost 18 million people who suffer from alcohol abuse or dependence. Alternatively, your son or daughter may be one of the more than 40% of college students who binge drink, many of whom experience blackouts, not remembering where they were, what they did, or with whom. You may know one of the 97,000 college students to experience alcohol-related sexual assault or heard the frustration of a college student trying to study while the alcohol-fueled party raged in the room next door. Many of us also have friends that grew up in a household where alcohol was a problem; in fact, 1 in 10 children in the U.S. grow up under such circumstances. Clearly, alcohol related problems are not reserved for the middle-aged, nor are they only experienced by those who drink.

RESEARCH

NIAAA supported research is advancing our understanding of alcohol-related problems across the lifespan. By translating this research into new and better prevention and treatment approaches we have the ability to enhance the well-being of individuals, their families, and society-at-large.

Much of what we have learned about alcohol use and alcohol use disorders in the U.S. population comes from analyses of NIAAA's National Epidemiologic Survey on Alcohol and Related Conditions (NESARC). Beginning in 2012, the third wave of NESARC will collect DNA samples in addition to detailed information on alcohol use, alcohol use disorders, and related physical and mental disabilities from an estimated 46,000 participants. This rich resource of genetic and other data will enable future studies comparing whole genome sequences to identify interactions between environmental and genetic risk factors that are associated with harmful alcohol use patterns and their associated disabilities. Survey data on the distribution of alcohol-related problems and treatment utilization will inform treatment delivery systems to better help those in need of services.

Research on individuals at different stages of life and at different points in the trajectory of their alcohol use and related problems underscores the importance of early identification and intervention in reducing future health problems. This is true for: children exposed to alcohol *in utero;* children and adolescents using alcohol and/or at high risk for alcohol-related problems; and individuals who exceed the low risk drinking guidelines, including those with alcohol dependence.

One of the barriers to intervening early with children with fetal alcohol spectrum disorders is identification of affected children given the wide range of physical, behavioral, and cognitive effects that may result from prenatal alcohol exposure. Ongoing studies are demonstrating the utility of fetal ultrasound and 3D facial image analysis for earlier and improved recognition of affected children. Alcohol has also been implicated in Sudden Infant Death Syndrome (SIDS) and stillbirth. In collaboration with NICHD and NIDCD, NIAAA is supporting studies to investigate this association and the role other environmental and maternal factors may play.

Children and adolescents who drink are also vulnerable to a number of adverse outcomes. These range from immediate consequences such as academic and social problems, injuries, and death, to longer-term consequences including increased risk for alcohol dependence. Nevertheless, alcohol use increases dramatically during adolescence. Given the range and severity of consequences associated with underage drinking and the prevalence of drinking and binge drinking, routine screening and intervention for alcohol use in young people is critical. Yet many pediatricians and family practitioners cite a lack of time, a lack of familiarity with screening tools, and a lack of confidence in their alcohol management skills as barriers to screening. NIAAA designed *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide* to help clinicians conduct fast, effective alcohol screens and brief interventions. The guide contains a new two-question screen and presents the first youth alcohol risk estimator chart, which combines information about a patient's age and drinking frequency to give a clinician a broad indication of the patient's chances for having alcohol-related problems. Coupled with what a clinician already knows about a patient, the risk estimator can help determine the depth and content of the clinician's response. The guide outlines different levels of intervention and presents an overview of brief motivational interviewing, an interactive, youth-friendly intervention that is considered to have the best potential

effectiveness for the adolescent population. Importantly, the guide has been endorsed and promoted by the American Academy of Pediatrics.

In addition to the acute consequences of underage drinking, there is increasing evidence that alcohol use during adolescence may result in enduring functional and structural changes in the brain. Studies to date, however, cannot differentiate between anomalies which resulted from adolescent alcohol exposure and those which predated it. NIAAA is embarking on a new multi-site initiative enlisting children and young adolescents before they begin to use alcohol and following them through adolescence. These studies will use advanced neuroimaging technology as well as neuropsychological and behavioral measures to assess alcohol's effects on brain development and associated cognitive, affective, and behavioral processes. NIAAA will continue to support complementary basic animal research on the effects of adolescent alcohol exposure on subsequent brain function and behavior into adulthood. Collectively these studies will provide a more complete picture of alcohol's effects on the developing brain and potentially provide insight into the association between early alcohol use and later alcohol dependence at the molecular and structural levels.

NIAAA continues to promote screening and brief intervention for adults and encourages inclusion of it in electronic health records. The primary goal is to identify and address high risk drinking behavior early, including advising individuals who do not meet criteria for alcohol dependence. By intervening early, providers are able to offer their patients more appealing, accessible options to address their alcohol problems, options that are less resource intensive and less expensive.

For those who continue to drink excessively, especially long term, the risk of alcoholic liver disease becomes a significant concern. In fact, 40% of patients with severe alcoholic hepatitis, a serious and potentially treatable form of alcoholic liver disease, die within six months of the onset of the clinical syndrome. NIAAA has launched a new initiative to foster close collaboration between basic scientists and clinicians expediting the translation of emerging findings into more effective treatment strategies. Of particular interest is the connection between the gut, liver, and brain and how perturbations to one organ may aggravate the disease state in another. NIAAA is supporting the integration of research to better understand the basic biological mechanisms that underlie the disease and the individual factors that contribute to disease susceptibility in clinical studies that will test new and improved strategies. The goal is to decrease the high mortality and morbidity associated with alcoholic hepatitis.

Developing effective treatments for alcohol dependence remains a high priority for NIAAA. Preliminary studies suggest that the smoking cessation drug varenicline (Chantix) could reduce drinking in alcohol dependent smokers. NIAAA is currently conducting a larger clinical trial with alcohol dependent smokers and non-smokers to assess safety and determine if varenicline reduces drinking in either group.

Kenneth R. Warren, Ph.D.
Acting Director, National Institute on Alcohol Abuse and Alcoholism

Dr. Kenneth R. Warren, Deputy Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), was named Acting Director of the Institute on November 1, 2008. The NIAAA is a component of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services.

Dr. Warren is a nationally-recognized expert on alcohol and pregnancy, and a long-time senior administrator at NIAAA. He joined the Institute in 1976 as a staff member of the then Division of Research. He later became Chief of the Biomedical Research Branch, and then Deputy Director of the Division of Extramural Research. From 1984 to 2005 he directed the Office of Scientific Affairs, which had responsibility for peer review, grants management, committee management, scientific communications, and the activities of the NIAAA National Advisory Council and Extramural Advisory Board. From 2002 to 2007, Dr. Warren served as Associate Director for Basic Research and, until late 2008, as Acting Director of the Institute's Office of Science Policy and Communications.

A graduate of the City College of New York, Dr. Warren earned his doctorate degree in Biochemistry from Michigan State University in 1970. He subsequently held postdoctoral positions at the University of California, Los Angeles and at University of Michigan Mental Health Research Institute before joining the Federal government in a research position at the Walter Reed Army Institute of Research in 1974.

Dr. Warren has maintained an active interest in all areas relating to alcohol and health, and often served as the editor of the triennial Reports to Congress on Alcohol and Health. He has been particularly active in research on the effects of alcohol use during pregnancy, including fetal alcohol syndrome (FAS) and fetal alcohol spectrum disorders (FASD). Dr. Warren initiated NIAAA's research program on FAS over 30 years ago. He currently chairs the government-wide Interagency Coordinating Committee on FAS.

Dr. Warren has received numerous honors, including a superior service award from the Public Health Service in 1982 for his work in development of the first Surgeon General's Advisory on FAS. In 1994, Dr. Warren received the Seixas Award from the Research Society on Alcoholism (RSA). In 2002, he received the Henry Rosett Award from the Fetal Alcohol Syndrome Study Group of RSA. In 2007, the National Organization on Fetal Alcohol Syndrome (NOFAS) honored Dr. Warren by placing his name into their Tom and Linda Daschle FASD Hall of Fame, followed by the receipt of the NOFAS Excellence Award in 2008.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Nora D. Volkow, M.D.
Director, National Institute on Drug Abuse

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIDA budget of $1,054,001,000 includes an increase of $1,887,000 over the comparable FY 2012 level of $1,052,114,000.

The President's Budget for FY 2013, which has just been released, offers a timely opportunity to review NIDA's research priorities for bringing the power of science to bear on drug abuse and addiction and reducing their burden on the public's health.

A TECHNOLOGICAL REVOLUTION

The technologies of biomedical research are advancing at unprecedented rates ushering in scientific breakthroughs that are providing a deeper understanding of human genetics, chemistry, and brain circuitry. The emerging picture has the potential to transform how we prevent and treat drug abuse and addiction and its health consequences, and involves new techniques for capturing and analyzing vast and diverse datasets on everything from genetics to neuroimaging to social networks.

NIDA is poised to harness complete genome and "deep" sequencing tools and a growing portfolio of epigenetic initiatives to elucidate how biological processes and environmental factors like chronic stress and drug exposure can alter the expression of genes that influence brain organization and function and the expression (or not) of substance use disorders. For example, the recent finding in an animal model that nicotine can trigger epigenetic processes that make the brain more susceptible to the effects of cocaine could have important policy and practice implications, if it occurs also in humans.

Epigenetic research is also shedding critical new light into the mechanisms that govern the disease progression of HIV, the spread of which is closely intertwined with injection and non injection drug use behaviors. A cure for HIV has been elusive because the virus is able to "hide" in a latent form in resting CD4-T cells. This allows HIV to persist for years, even with prolonged exposure to antiretroviral drugs. Understanding this "latency" effect could enable researchers to reactivate the virus and use current or future therapies to rid the body of it altogether.

The overlaying of neuroimaging data will further accelerate discovery by linking molecular and cellular data with human behavior. For example, a new functional magnetic resonance imaging (fMRI)-based approach can probe the resting brain (i.e., one not performing any specific task) to illuminate circuit-level functions that may prompt behavioral responses, including those related to diseased states or vulnerability. Individual differences found in these images could provide useful biomarkers (neural signatures) of illness risk, course, and treatment response.

The amount and diversity of data being generated by genetic, epigenetic, and imaging studies call for harmonization standards that will allow data integration across laboratories. Thus, our continuing efforts to train the next generation of addiction researchers must now take into account the urgent need for a new cadre of interdisciplinary scientists capable of developing modern analytical tools for integrating and managing large pooled data sets and for modeling and analyzing complexity.

THERAPEUTICS DEVELOPMENT

To help those already suffering from addiction, we need to expand the tools available to treat substance use disorders and their health consequences. To this end, NIDA will continue to invest in the development of addiction medications and to seek public-private partnerships with pharmaceutical companies still reluctant to play an active role due to perceived stigma and financial disincentives. Success demands both adaptable and novel approaches.

Among the "low-hanging fruit" are already-approved drugs, which NIDA is seeking to repurpose for addiction indications, saving enormous amounts of research and development time and cost. Notable in this category are: buspirone, which blocks action at the dopamine (D_3) receptor (among its other effects) and may be useful in treating stimulant addiction, based on well-established findings in the animal literature; and cytisine, which acts on nicotinic receptors and has recently been shown to be about 3.5 times more effective than placebo in a smoking cessation trial.

NIDA also continues to support research to increase the effectiveness of various vaccines being tested against nicotine, cocaine, heroin, and methamphetamine. Efforts aim to increase these vaccines' immunogenicity—that is, their ability to stimulate the production of antibodies capable of blocking a drug's entry into the brain.

Finally, NIDA is actively pursuing a strategy that involves the use of medication combinations, an approach that has proven effective for treating many diseases (e.g., HIV, cancer) and one starting to show success with addiction. For example, the combination of lofexidine (a hypertension medication) and marinol (a synthetic form of marijuana's THC) has shown promise in treating withdrawal symptoms (which can trigger relapse) among marijuana-addicted individuals.

IMPROVING PUBLIC HEALTHCARE: DELIVERY AND PERFORMANCE

NIDA will harness every opportunity to translate scientific knowledge to improve strategies for combating drug abuse and addiction. This commitment includes engaging physicians as "frontline" responders and providing them with tested tools, including a Web-based screening tool that generates specific clinical recommendations. The broad availability of these resources is an important step toward integrating substance abuse screening, brief intervention, and referral to treatment (SBIRT) into routine medical care, which will enable better healthcare decisions and outcomes.

NIDA will also capitalize on the Affordable Care Act to study how innovations in service delivery, organization, and financing can improve access to and use of effective prevention and treatment interventions. Because so few people access treatment, coupled with the >$600 billion that drug abuse and addiction cost society each year, even a marginal increase in treatment use and retention could have a sizeable public health impact—for individuals, families, and society as a whole.

To help get evidence-based treatments to providers in a variety of settings, NIDA uses collaborative research infrastructures designed to deploy proven strategies rapidly and effectively. For example, NIDA's Criminal Justice-Drug Abuse Treatment Studies (CJ-DATS) network promotes multilevel collaborations to test proven treatment models in the criminal justice system, disproportionately affected by both drug abuse and HIV. One example, called "Seek, Test, Treat, and Retain," expands access to HIV testing and treatment, ultimately reducing HIV spread.

STAYING AHEAD OF THE CURVE

NIDA continues to monitor drug abuse trends across different populations. Particularly worrisome are the trends pertaining to marijuana use, on the rise after about a decade of decline; the emergence of an ever-evolving array of synthetic drugs (e.g., spice and bath salts) that are sending users to emergency rooms nationwide; and the continued high rates of prescription drug abuse, which have resulted in a quadrupling in unintentional overdose deaths in this country since 1999. NIDA is addressing all these problems through both broad-based prevention efforts and targeted initiatives.

Prescription drug abuse is one such targeted area that demands a multifaceted approach. **NIDA's long term strategy to help reverse this trend includes: (1)** research to understand the factors that influence an individual's risk, treat those already addicted, and develop pain medications with reduced abuse potential; (2) physician education to improve pain treatment while minimizing prescription drug abuse; and (3) community engagement exemplified by NIDA's leadership of a multiagency effort to create a Surgeon General *Call to Action* to reduce prescription drug abuse among youth.

In closing, NIDA pledges to continue to tackle the emerging and significant public health needs related to drug abuse and addiction, taking advantage of

unprecedented scientific opportunities to close the gaps in our knowledge and develop and disseminate more effective strategies to prevent and treat drug abuse and addiction.

Nora D. Volkow, M.D.
Director, National Institute on Drug Abuse

Nora D. Volkow, M.D., became Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health in May 2003. NIDA supports most of the world's research on the health aspects of drug abuse and addiction.

Dr. Volkow's work has been instrumental in demonstrating that drug addiction is a disease of the human brain. As a research psychiatrist and scientist, Dr. Volkow pioneered the use of brain imaging to investigate the toxic effects of drugs and their addictive properties. Her studies have documented changes in the dopamine system affecting the actions of frontal brain regions involved with motivation, drive, and pleasure and the decline of brain dopamine function with age. She has also made important contributions to the neurobiology of obesity, ADHD, and the behavioral changes that occur with aging.

Dr. Volkow was born in Mexico, attended the Modern American School, and earned her medical degree from the National University of Mexico in Mexico City, where she received the Premio Robins award for best medical student of her generation. Her psychiatric residency was at New York University, where she earned the Laughlin Fellowship Award as one of the 10 Outstanding Psychiatric Residents in the USA.

Dr. Volkow spent most of her professional career at the Department of Energy's Brookhaven National Laboratory (BNL) in Upton, New York, where she held several leadership positions including Director of Nuclear Medicine, Chairman of the Medical Department, and Associate Director for Life Sciences. In addition, Dr. Volkow was a professor in the Department of Psychiatry and Associate Dean of the Medical School at the State University of New York (SUNY)-Stony Brook.

Dr. Volkow has published more than 500 peer-reviewed articles and more than 90 book chapters and non-peer reviewed manuscripts, and has also edited three books on the use of neuroimaging in studying mental and addictive disorders.

During her professional career, Dr. Volkow has been the recipient of multiple awards, including her selection for membership in the Institute of Medicine in the National Academy of Sciences and the International Prize from the French Institute of Health and Medical Research for her pioneering work in brain imaging and addiction science. She was recently named one of Time Magazine's "Top 100 People Who Shape our World" and was included as one of the 20 people to watch by Newsweek magazine in its "Who's Next in 2007" feature. She was also included in Washingtonian Magazine's 2009 and 2011 list of the "100 Most Powerful Women" and named "Innovator of the Year" by U.S. News & World Report in 2000.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Thomas R. Insel, M.D.
Director, National Institute of Mental Health
Acting Director, National Center for Advancing Translational Sciences

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Mental Health (NIMH) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIMH budget of $1,479,204 represents an increase of $701,000 over the comparable FY 2012 level of $1,478,503. In my statement, I will underscore the scope of mental disorders in the United States and their impact on public health; outline examples of NIMH's research efforts designed to address this challenge; and, highlight the next generation of researchers that are advancing us toward this goal.

PUBLIC HEALTH BURDEN OF MENTAL ILLNESS

The National Institute of Mental Health (NIMH) is the lead Federal agency for research on mental and behavioral disorders, with a mission to transform the understanding and treatment of mental illnesses through basic and clinical research. The global burden of mental illness is enormous. In the United States alone an estimated 11 million American adults (approximately 5 percent of all adults) suffer from a seriously disabling mental illness each year.[21] Mental disorders are the leading cause of disability in the United States and Canada, accounting for 24 percent of all years of life lost to disability and premature mortality (Disability Adjusted Life Years or DALYs).[22] The personal, social and economic costs associated with these disorders are tremendous. Suicide is the 10th leading cause of death in the United States, accounting for the loss of more than 36,000 American lives each year, more than double the number of lives lost to homicide.[23] A cautious estimate places the direct and indirect financial costs associated with mental illness in the U.S. at well over $300 billion annually, and it ranks as the third most costly medical condition in terms of overall health care expenditure, behind only heart conditions and traumatic injury.[24,25] Even more concerning, the burden of illness

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[21] Substance Abuse and Mental Health Services Administration. *Results from the 2009 National Survey on Drug Use and Health: Mental Health Findings* (Office of Applied Studies, NSDUH Series H-39, HHS Publication No. SMA 10-4609). Rockville, MD: Substance Abuse and Mental Health Services Administration, 2010.
[22] The World Health Organization. *The global burden of disease: 2004 update*, Table A2: Burden of disease in DALYs by cause, sex and income group in WHO regions, estimates for 2004. Geneva, Switzerland: WHO, 2008.
[23] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS): www.cdc.gov/ncipc/wisqars accessed November 2011.
[24] Insel TR. Assessing the economic cost of serious mental illness. *Am J Psychiatry*. 2008 Jun;165(6):663-5.
[25] Soni A. *The Five Most Costly Conditions, 1996 and 2006 Estimates for the U.S. Civilian Noninstitutionalized Population*. Statistical Brief #248. July 2009. Agency for Healthcare Research and Quality, Rockville, MD.

for mental disorders is projected to sharply increase, not decrease, over the next 20 years.[26]

Disorders such as schizophrenia, bipolar disorder, depression, autism spectrum disorder, post-traumatic stress disorder, eating disorders, and borderline personality disorder are serious, life-threatening illnesses. In order to advance improved diagnostic tests, more effective treatments, and better prevention strategies, NIMH is supporting research initiatives that build upon and expand our knowledge gained from basic brain and behavioral research and using these findings to develop innovative treatments that pave the way toward prevention, recovery, and cure.

INVESTING IN BASIC RESEARCH

While NIMH's ultimate goal is to improve public health, the first step toward this goal lies in conducting basic research. This research is focused on understanding the most fundamental aspects of human biology, at the molecular, cellular, and circuit levels. We have witnessed exciting progress over the past decade in brain research, yet we have barely begun to scratch the surface in understanding the human body's most complex organ. Recent findings, however, offer significant encouragement. For example, to better understand how patterns of gene expression influence the developing brain, NIMH supported the first map of gene expression across the life span. Researchers using this map have found that nearly 90 percent of genes are expressed *differently* during prenatal development, infancy, and childhood. While each of these developmental stages has a distinct molecular signature, the fetal brain looks like an entirely different organ when compared to the postnatal brain. NIMH researchers have also shown that these differences in gene expression are likely caused by DNA methylation—a regulatory mechanism that switches genes from "off" to "on" during the pivotal transition from fetal to postnatal life. Regulatory mechanisms like methylation leave chemical instructions that tell genes what proteins to make, what kind of tissue to produce, or what functions to activate. This process may be particularly sensitive to environmental influences during this critical early life period. In the prenatal brain, genes help to shape the circuitry for learning, memory, and cognition - functions that become disturbed in developmental brain disorders. Genes that code for the enzymes that carry out methylation, for example, have been implicated in schizophrenia.

ADVANCING TRANSLATIONAL SCIENCES

NIMH's next step toward improving public health involves harnessing the advances made through basic research and translating them into new and improved treatments and prevention strategies. Autism Spectrum Disorder (ASD) includes a group of complex neurodevelopmental disorders that range in severity and that are characterized by social impairments, communication difficulties, and often feature restricted, repetitive, and stereotyped patterns of behavior. To help address this important

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[26] Bloom DE, Cafiero ET, Jané-Llopis E, Abrahams-Gessel S, Bloom LR, Fathima S, Feigl AB, Gaziano T, Mowafi M, Pandya A, Prettner K, Rosenberg L, Seligman B, Stein A, Weinstein C. *The Global Economic Burden of Non-communicable Diseases*. Geneva, Switzerland: World Economic Forum, 2011.

challenge, NIMH established an intramural research program to accelerate development and testing of innovative treatments for ASD. This program has already evaluated hundreds of children and tested three novel compounds to treat symptoms related to ASD.

In many disorders, such as ASD, prevention is not yet fully effective or even possible. Current medications reduce symptoms but are not sufficient for recovery in most cases. Unfortunately, over the past few years most pharmaceutical companies moved away from research and development of new medications for mental illness, reducing the hope of discovering more effective medications. To catalyze the development of the next generation of medications, NIMH will create a network of centers for rapid early phase testing of promising compounds for serious mental illness and autism. This effort will be integrated with the Research Domain Criteria (RDoC) project in which NIMH is taking an experimental approach for the classification of mental disorders and the identification of new targets for treatment.

IMPROVING PUBLIC HEALTH

NIMH is committed to improving the nation's public health. This is demonstrated through dedication to basic and translational research on the brain and behavior, and captured as well through the Institute's broader public health efforts. Suicide, for example, represents one of the leading causes of death in the United States. To combat this problem, NIMH is spearheading several initiatives intended to reduce suicide. For example, NIMH is taking a lead role with The National Action Alliance for Suicide Prevention, a public-private partnership tasked with developing the next National Strategy for Suicide Prevention. Alongside the Jed Foundation, NIMH is co-chairing the Action Alliance's Research Task Force, and developing a research agenda to reduce suicide morbidity (attempts) and mortality (deaths) by at least 20 percent in five years, and 40 percent or more in 10 years.

One of the most notable and disturbing increases in suicide over the past decade has occurred among the nation's returning military veterans. To counter this trend, NIMH has partnered with the Department of the Army to conduct the Army Study to Assess Risk and Resilience in Servicemembers (Army STARRS) Project - the largest study of mental health risk and resilience ever conducted among military personnel. This project, a cooperative agreement led by NIMH, is working to identify factors related to risk for suicide among Army soldiers. Results from Army STARRS will contribute significantly to our understanding of risk and resilience associated with suicide and point the way toward more effective prevention, both within the Army and among the broader adult population.

ENCOURAGING NEW INVESTIGATORS

Fundamental discoveries and their translation to treatments will only take place if we invest in a well-trained workforce of innovators. NIMH remains committed to ensuring that the next generation of researchers is fully trained and ready to take up the

mantle of this important challenge. NIMH recently launched an administrative supplement program that supports advanced research experiences for outstanding early career physicians and medical students from diverse backgrounds. The goal of the program is to improve the diversity of the mental health research workforce by supporting and recruiting early-stage investigators from groups that have been shown to be underrepresented in science. Participation in this program will enhance the professional development of the investigators, sustain their career trajectory through research independence, and lead to scientific advances that will further transform our understanding and treatment of mental illness.

From basic science to major public health initiatives, the research that NIMH supports is setting the stage for the precision medicine of the future, and aims to prevent or cure mental disorders with targeted interventions grounded in neuroscience.

Thomas R. Insel, M.D.
Director, National Institute of Mental Health
Acting Director, National Center for Advancing Translational Sciences

Thomas R. Insel, M.D., is Director of the National Institute of Mental Health (NIMH), the component of the National Institutes of Health charged with generating the knowledge needed to understand, treat, and prevent mental disorders. His tenure at NIMH has been distinguished by groundbreaking findings in the areas of practical clinical trials, autism research, and the role of genetics in mental illnesses.

Prior to his appointment as NIMH Director in the Fall 2002, Dr. Insel was Professor of Psychiatry at Emory University. There, he was founding director of the Center for Behavioral Neuroscience, one of the largest science and technology centers funded by the National Science Foundation and, concurrently, director of an NIH-funded Center for Autism Research. From 1994 to 1999, he was Director of the Yerkes Regional Primate Research Center in Atlanta. While at Emory, Dr. Insel continued the line of research he had initiated at NIMH studying the neurobiology of complex social behaviors. He has published over 250 scientific articles and four books, including the Neurobiology of Parental Care (with Michael Numan) in 2003.

Dr. Insel has served on numerous academic, scientific, and professional committees and boards. He is a member of the Institute of Medicine, a fellow of the American College of Neuropsychopharmacology, and is a recipient of several awards, including the Outstanding Service Award from the U.S. Public Health Service and the 2010 La Fondation IPSEN Neuronal Plasticity Prize. Dr. Insel graduated from the combined B.A.-M.D. program at Boston University in 1974. He did his internship at Berkshire Medical Center, Pittsfield, Massachusetts, and his residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Eric D. Green, M.D., Ph.D.
Director, National Human Genome Research Institute

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Human Genome Research Institute (NHGRI) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NHGRI budget of $511,370,000 includes a decrease of $893,000 below the comparable FY 2012 level of $512,263,000.

It is an extraordinary time for the field of genomics. Through recent scientific advances and technological developments, we are gaining a deeper understanding for how the human genome plays a central role in health and disease, enabling investigators across the biomedical research spectrum to pursue new avenues for translating this knowledge into clinical applications. NHGRI, guided by an ambitious vision for genomics research that the Institute published in February 2011, is poised to lead a research agenda in FY 2013 that will focus not only on basic genome biology and the genomic underpinnings of disease, but will also seek to develop strategies for applying genomics to advance medical science and, ultimately, to improve the effectiveness of healthcare.

ENSURING A STRONG FOUNDATION

The unprecedented decreases in the cost of DNA sequencing—resulting from NHGRI-stimulated technology development coupled with myriad innovations by the NHGRI Large-Scale Genome Sequencing Centers—have fundamentally changed how genomic data is now generated as part of biomedical research. Whereas sequencing that first human genome during the Human Genome Project cost upwards of a billion dollars, sequencing a human genome using recently developed technologies will soon cost $1,000 (or less).

The recent renewal of the program supporting the NHGRI Large-Scale Genome Sequencing Centers ensures the productive continuation of flagship initiatives such as The Cancer Genome Atlas (TCGA) in addition to special projects with specialists focusing on specific disorders, such as Alzheimer's disease. These centers will continue to develop innovative methodologies and information management systems, which will inevitably lead to further reductions in the cost of genome sequencing. With such reductions will come the opportunity to sequence the tens of thousands of individual genomes required to understand the small genetic differences that cumulatively confer risk for common diseases, such as diabetes and heart disease. Furthermore, the

accessibility of low-cost DNA sequencing technologies will be essential for making genome sequencing a routine part of clinical care.

To facilitate the utilization of genomic tools and information for exploring biological questions and ultimately improving clinical care, the NHGRI Centers of Excellence in Genomic Science will conduct interdisciplinary research and training initiatives focused on the production, analysis, and utilization of genomic data. From these efforts, new insights into the complexity of human genome function are emerging, and these in turn are benefiting the research community at large. Similarly, the human-centric ENCyclopedia of DNA Elements (ENCODE) project and the companion model organism ENCODE project (modENCODE) will continue to build a 'knowledge base' that details the functional genomic elements underlying biological processes in humans as well as organisms that serve as important models for studying human biology.

To complement the requisite understanding of normal genome function established by these projects, tools for defining the genetic contributions to human disease are being developed. NHGRI continues to lead efforts within the international 1000 Genomes project to build a deep catalog of genomic variants among different human populations; in turn, this information will be used to identify the subsets of rare and common variants that confer risk for (or protection from) specific diseases or adverse drug responses. FY 2013 will also see the key maturation of the Human Heredity and Health in Africa (H3Africa) initiative, an NIH Common Fund project managed by NHGRI. The increased knowledge generated about genomic variation and the complex interactions between environmental and genetic factors in African populations will enhance understanding of disease predispositions and drug responses for all human populations.

If genomics is to be a powerful contributor to studies being performed across the biomedical research community, researchers must be able to process and analyze the massive amounts of genomic data that they can now readily produce. NHGRI will pursue the establishment of pioneering approaches for data management and analysis via the development and refinement of bioinformatic tools, resources, and standards.

TRANSLATING THE POTENTIAL

The Genome Sequencing Program continues to be a prominent and vibrant part of the Institute's research portfolio. Looking ahead, it will play an increased role in translating genomic-based capabilities to understand disease biology. The Program's renewal in FY 2012 included not only continued support for medical sequencing projects, but also a charge to conduct collaborative research projects with other investigators to broaden the application of genome sequencing as a tool for unraveling the genomic basis of human disease. The prototype for the latter is TCGA, a collaboration with the National Cancer Institute to identify the genomic basis of many different forms of human cancer.

The renewal of NHGRI's Genome Sequencing Program also included establishment of new Mendelian Disorders Genome Centers focused on rare, single-gene (called Mendelian) diseases. These new centers will seek to establish the genetic basis for thousands of rare disorders (affecting millions of Americans) for which the genetic defects remain unknown. Recent advances in genome sequencing offer the hope that the genetic underpinnings for most of these rare diseases can be identified through focused research efforts that were not possible or affordable with previous genome sequencing technologies.

PREPARING FOR GENOMIC MEDICINE

To capitalize on its growing foundation of basic and translational research, NHGRI recently launched the Clinical Sequencing Exploratory Research projects, a new component of the Institute's Genome Sequencing Program. The new projects will investigate how to utilize genomic knowledge in medical settings and begin to explore how healthcare professionals can routinely use genome sequence information for patient care. A related effort, the Electronic Medical Records and Genomics (eMERGE) Network, is pursuing how patients' genomic information can be linked to disease characteristics and symptoms in their electronic medical records, providing the ability to explore associations with disease pathologies and eventually to improve patient care.

Key to the ultimate success in all of these endeavors will be continued attention to the societal implications of advancing genomic technologies and understanding. Deliberate, ongoing engagement by laboratory, clinical, and social scientists and scholars in ethics, law, and philosophy with the public must remain a priority.

Through its portfolio of basic and translational research, the Institute is pushing forward the boundaries of our knowledge and defining the issues that must be addressed before genomics is routinely deployed as a standard element in medical care. NHGRI is leading this charge by funding ambitious research programs to understand the structure and function of genomes more fully, to use genomics as a central tool for understanding the biology of disease, and to establish the path for the implementation of genomic medicine. In all of these pursuits, the Institute maintains a laser-like focus on its ultimate mission—to improve human health through genomics research.

Eric D. Green, M.D., Ph.D.
Director, National Human Genome Research Institute

Eric D. Green, M.D., Ph.D. is the Director of the National Human Genome Research Institute (NHGRI) at the National Institutes of Health (NIH) in Bethesda, Maryland, a position he has held since late 2009. Previously, he served as the NHGRI Scientific Director (2002-2009), Chief of the NHGRI Genome Technology Branch (1996-2009), and Director of the NIH Intramural Sequencing Center (1997-2009).

Born and raised in St. Louis, Missouri, Dr. Green received his B.S. degree in Bacteriology from the University of Wisconsin-Madison in 1981, and his M.D. and Ph.D. degrees from Washington University in 1987. During residency training in clinical pathology (laboratory medicine), he worked in the laboratory of Dr. Maynard Olson, where he launched his genomics research program. In 1992, he was appointed an assistant professor of pathology and genetics as well as a co-investigator in the Human Genome Center at Washington University. In 1994, he joined the newly established Intramural Program of the National Center for Human Genome Research at the NIH, later renamed the National Human Genome Research Institute.

Honors given to Dr. Green include a Helen Hay Whitney Postdoctoral Research Fellowship (1989-1990), a Lucille P. Markey Scholar Award in Biomedical Science (1990-1994), induction into the American Society for Clinical Investigation (2002), the Lillian M. Gilbreth Lectureship for Young Engineers at the National Academy of Engineering (2001), an Alumni Achievement Award from Washington University School of Medicine (2005), and induction into the American Association of Physicians (in 2007). He is a Founding Editor of the journal Genome Research (1995-present) and a Series Editor of Genome Analysis: A Laboratory Manual (1994-1998), both published by Cold Spring Harbor Laboratory Press. He is also Co-Editor of Annual Review of Genomics and Human Genetics (since 2005). Dr. Green has authored and co-authored over 250 scientific publications.

From the early 1990s, Dr. Green's research program was at the forefront of efforts to map, sequence, and understand eukaryotic genomes. His work included significant, start-to-finish involvement in the Human Genome Project. More recently, Dr. Green established a program in comparative genomics that involved the generation and comparative analyses of sequences from targeted genomic regions in multiple evolutionarily diverse species. His laboratory utilized its own mapping and sequence data to identify and characterize several human disease genes, including those implicated in certain forms of hereditary deafness, vascular disease, and inherited peripheral neuropathy. Most recently, Dr. Green led a number of efforts utilizing contemporary strategies for large-scale DNA sequencing to study genomic variation among humans (in particular, relating to genetic disease) and to examine the microbial communities (i.e., the microbiomes) that exist in and on the human body.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Roderic I. Pettigrew, Ph.D., M.D.
Director, National Institute of Biomedical Imaging and Bioengineering

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIBIB budget of $336,896,000 is $1,058,000 below the comparable FY 2012 level of $337,954,000.

The mission of NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. NIBIB invests resources in scientific and technological research opportunities at the convergence of the physical, quantitative and life sciences, and in training the next generation of researchers. The Institute is at the forefront of translating scientific advances into engineered medical solutions. Ultimately, NIBIB seeks to realize innovations that address healthcare challenges, reduce disease mortality and morbidity, and enhance quality of life. To accomplish this goal, NIBIB continues to fund bold and far-reaching projects that facilitate discovery and translate basic science into better healthcare.

DISCOVERY SCIENCE AND TECHNOLOGIES TO EMPOWER PATIENTS

Neurostimulation Research in Paraplegics: Recovery of Voluntary Motion, Bladder and Sexual Function: Through the NIBIB Rehabilitation Engineering program, researchers from the University of California, Los Angeles, have developed a high density electrode array technology for epidural stimulation of the spinal cord. The first patient, the victim of a car accident that left him *completely paralyzed from the chest down*, received electrical stimulator implants in his lower back. Over a one-year period, he received daily electrode stimulating sessions with specific tasks and movements being performed, which is known as locomotor training. The procedure resulted in independent standing, some voluntary leg control, and regained bladder, bowel, and sexual function. It is believed that the epidural stimulation and locomotor training have two distinct roles. The stimulation appears to switch on intact circuits in the spinal cord, while the training relays specific information about body and limb positions. The investigators have applied this technology to three patients with complete spinal cord injury. All patients are able to stand and voluntarily control both legs in the presence of epidural stimulation.

Wireless Tongue Drive System Could Provide Independence to Paralyzed Patients: Assistive technologies (ATs) have been available to control devices used for daily living such as powered wheelchairs and computers. However, many of these devices have

limited commands, cause rapid muscle fatigue, or interfere with the user's basic functions. NIBIB-funded researchers from the Georgia Institute of Technology have developed a tongue-operated AT called the Tongue Drive System (TDS) that is unobtrusive, wearable, wireless, and can substitute for many arm and hand functions. The core TDS technology exploits the fact that even a person with severe paralysis that impairs breathing and speech can still move their tongue and therefore, can fully utilize this extraordinary system. The device consists of a headset, a compact computer, and a tiny magnet attached to the tongue. Tongue movements change the magnetic field around the mouth. These changes are detected by magnetic sensors in the headset, relayed to the computer, and translated into the commands of the user. The system allows users to control various devices and perform numerous tasks such as drive their wheelchairs, operate their computers, and generally control their environment in an independent fashion. The TDS can be linked to currently available technologies such as a smart phone, to control household appliances, lights, locks, heating/air conditioning, as well as prosthetic arms or legs. This remarkable technology could offer paralyzed individuals an unprecedented level of independence for leading active, productive lives.

TECHNOLOGIES TO ACCELERATE THERAPEUTICS DEVELOPMENT

Multi-Layered Nanoparticles for Specific Delivery of Drugs to Tumors: An important area of investigation supported by NIBIB is targeted drug delivery, e.g., to cancer cells and not the surrounding normal tissue. One group of investigators has created multilayered nanoparticles that can be delivered systemically (by venous injection) but act only at the site of the tumor due to the specific chemical properties of each layer and their interaction with the specific biochemistry of tumor cells. The properties of the outer surface layer were designed to provide a surface that promotes distribution of particles throughout the body and shields the drug while preventing binding to healthy tissues. This outer "stealth" layer is also pH-sensitive and is shed in the acidic environment of tumors exposing the toxic load of the nanoparticle. At the site of a tumor, the shed surface layer reveals a charged nanoparticle layer, which contains the anti-cancer agent and is readily taken up by tumor cells. The investigators have demonstrated that this concept for tumor targeting is applicable to a broad range of cancers and compatible with various therapies designed to be triggered by acidic tumor tissue. Because particles can be designed with layers that can be shed in specific environments, the cancer drug can be exposed and delivered directly to the tumor, which makes this emerging technology an extremely promising cancer drug delivery technique.

Nanoscale Theranostics: Delivering Treatment and Monitoring Efficacy Simultaneously: Recent advances in nanoscience have spurred new developments in the field of theranostics (the combination of both therapeutic and diagnostic functions in a single system). These integrated systems have been shown to selectively transport therapeutic agents to target tissues while simultaneously monitoring biological responses to the delivered therapy. The current challenge is to develop systems or "platforms" that allow the optimization of the function of each of the combined molecular components that target the disease site, deliver the therapy, and allow for imaging of the results immediately. Researchers recently developed a nanoscale delivery platform known as

polymer-caged nanobins (PCNs). The surface of PCNs can be chemically modified to attach a variety of molecules in order to target specific cells or tissues. The platform is liposome based, which allows for a simplified loading and encapsulation of a range of therapeutic drugs. To allow monitoring of the response to therapy, the PCN shell contains magnetic resonance imaging (MRI) contrast agents, which provide images of the drug targets as well as real time images of the response to the drug, e.g., reduction in tumor size. This type of theranostic can make the treatment of numerous diseases safer and more successful because the prescribed regimens can be adjusted in real time during treatment.

ACCELERATING EARLY DIAGNOSIS AT THE POINT-OF- CARE

Hand-Held Nuclear Magnetic Resonance (NMR) for Rapid Point-Of-Care Diagnostics: One of the major challenges in medicine is the rapid and accurate measurement of proteins that are biomarkers of a specific disease, or pathogens in biological samples. Magnetic particles which target biomarkers are attractive candidates for such biosensing applications because most biological samples do not have any background magnetization that would interfere with detection. A hand-held micro-NMR device, which can detect such particles, has recently been developed for rapid ~½ hr analysis of a variety of biologics, from bacteria identification in small fluid samples to protein markers of cancer. The device employs magnetic particles that bind to targets of interest, creating a signal detectable by the micro-NMR. Also known as diagnostic magnetic resonance (DMR), this powerful biosensor technology offers unique advantages, such as robust signal amplification, broad applicability to profile different types of targets (DNA, proteins, metabolites, and cells), minimal sample preparation, ability to perform measurements in turbid media, and high-throughput capacity. Importantly, the low cost and ability to use the device at the point-of-care could make important contributions to the battle against serious public health issues such as tuberculosis and HIV in underserved populations. In an early study of patients with unknown solid masses, the diagnosis of cancer was made at the bedside in ~ ½ hr and with higher accuracy than with the traditional method of tissue biopsy which requires two days for final results.

NEW INVESTIGATORS, NEW IDEAS

NIBIB Design by Biomedical Undergraduate Teams (DEBUT) Challenge: The DEBUT challenge is a new NIBIB program opened to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. The main goals of the challenge are: 1) to provide undergraduate students experience in working in teams to identify unmet clinical needs, and design, build and debug solutions for open-ended problems; 2) to generate novel, innovative tools to improve healthcare, consistent with NIBIB's mission; and 3) to highlight and acknowledge the contributions and accomplishments of undergraduate students. Entries have been solicited in three categories: Diagnostic Devices and Methods; Therapeutic Devices and Methods; and Technologies to Aid Underserved Populations and Individuals with Disabilities. The winning student team in each category will receive a $10,000 prize

at the NIBIB DEBUT Award Ceremony during the annual conference of the Biomedical Engineering Society.

Roderic I. Pettigrew, Ph.D., M.D.
Director, National Institute of Biomedical Imaging and Bioengineering

Roderic I. Pettigrew, Ph.D., M.D., is the first Director of the National Institute of Biomedical Imaging and Bioengineering. Prior to his appointment at the NIH, he was Professor of Radiology, Medicine (Cardiology) at Emory University and Bioengineering at the Georgia Institute of Technology and Director of the Emory Center for MR Research, Emory University School of Medicine, Atlanta, Georgia.

Dr. Pettigrew is known for his pioneering work at Emory University involving four-dimensional imaging of the cardiovascular system using magnetic resonance (MRI). Dr. Pettigrew graduated cum laude from Morehouse College with a B.S. in Physics, where he was a Merrill Scholar; has an M.S. in Nuclear Science and Engineering from Rensselear Polytechnic Institute; and a Ph.D. in Applied Radiation Physics from the Massachusetts Institute of Technology, where he was a Whitaker Harvard-MIT Health Sciences Scholar. Subsequently, he reccived an M.D. from the University Of Miami School Of Medicine in an accelerated two-year program, did an internship and residency in internal medicine at Emory University and completed a residency in nuclear medicine at the University of California, San Diego. Dr. Pettigrew then spent a year as a clinical research scientist with Picker International, the first manufacturer of MRI equipment. In 1985, he joined Emory as a Robert Wood Johnson Foundation Fellow with an interest in non-invasive cardiac imaging.

Dr. Pettigrew's awards include membership in Phi Beta Kappa, the Bennie Award (Benjamin E. Mays) for Achievement, being named the Most Distinguished Alumnus of the University of Miami in 1990, The University of Miami Miller Medical School Hall of Fame and The Biomedical Engineering Society Distinguished Achievement Award. In 1989, when the Radiological Society of North America celebrated its 75th Diamond anniversary scientific meeting, it selected Dr. Pettigrew to give the keynote Eugene P. Pendergrass New Horizons Lecture. He has also served as chairman of the Diagnostic Radiology Study Section, Center for Scientific Review, NIH. He has been elected to membership in, both the Institute of Medicine, and the National Academy of Engineering of the National Academies, fellowship in the American Heart Association, American College of Cardiology, American Institute for Medical and Biological Engineering, International Society for Magnetic Resonance in Medicine, and Honorary Fellow of the Biomedical Engineering Society.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Josephine P. Briggs, M.D.
Director, National Center for Complementary and Alternative Medicine

Mr. Chairman and Members of the Committee:

As the Director of the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health (NIH), I am pleased to present the President's budget request for NCCAM. The FY 2013 budget includes $127,930,000, which is $26,000 over the comparable FY 2012 level of $127,904,000.

The landscape of our health care system is changing in many important ways. Among them is a clear trend toward incorporation of complementary health practices, which often have origins outside of conventional medicine, into integrative approaches to care. There are a number of factors—including consumer demand and emerging scientific evidence—driving these changes. Nonetheless, there are compelling needs of the public, health care providers, and policymakers for good scientific evidence on the safety and potential benefit of these complementary and integrative approaches. Using the highest standards of scientific rigor, NCCAM is committed to developing evidence about practices that are being integrated into health care. We are particularly interested in those cases where there is scientific opportunity and/or important public health need.

TRENDS IN COMPLEMENTARY AND INTEGRATIVE HEALTH CARE

National surveys conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention show that nearly 40 percent of Americans report using one or more practices such as acupuncture, massage, yoga, meditation, spinal manipulation, dietary supplements or herbal medicines to help manage their health and wellness. Similarly, data show that health care systems and providers are incorporating such interventions. For example, an American Hospital Association survey conducted in 2007 showed that 37 percent of hospitals offered complementary modalities; and a national study reported last year by the NCHS reported widespread availability of complementary approaches in hospice settings. Other data from the Departments of Defense (DOD) and Veterans Affairs (VA) show increasing use of complementary modalities in their populations. According to the VA, 89 percent of their facilities offered complementary therapies in 2011. Both the DOD and VA have integrated complementary modalities into the care of patients with posttraumatic stress and sleep disorders, and to improve treatment of pain.

REDUCING PAIN AND IMPROVING SYMPTOM MANAGEMENT

One area of urgent public health need is better strategies for managing chronic pain. According to the Institute of Medicine, chronic pain affects an estimated 116 million Americans, and costs the Nation approximately $635 billion each year.[27] Chronic pain is the most frequently cited reason for which Americans use complementary health practices. For many individuals suffering from chronic pain, conventional approaches provide incomplete relief. Furthermore, pharmacological treatment with opioids or anti-inflammatory drugs can have significant adverse effects. There is now emerging evidence, much of it from NCCAM-supported studies, that some nonpharmacological interventions, such as massage, spinal manipulation, yoga, meditation, and acupuncture, may be helpful in treating chronic pain. Additional scientific evidence is needed to better understand these findings, and the optimal use and safety of these integrative approaches.

To this end, NCCAM is supporting a growing portfolio of studies on the use of nonpharmacological interventions for the management of chronic pain, including back and neck pain and pain associated with osteoarthritis, fibromyalgia, and headaches. In addition, we are supporting research to better understand the biological mechanisms by which complementary modalities may contribute to management of pain and other symptoms. For example, we recently funded Centers of Excellence for Research on Complementary and Alternative Medicine that use advanced functional and structural neuroimaging technologies to study pain. NCCAM is also providing leadership to a working group within the trans-NIH Pain Consortium to develop standards for research on chronic low back pain. Finally, in the next year, NCCAM plans to focus its intramural research program on understanding the role of the brain in chronic pain syndromes. The program will be highly collaborative with other intramural neuroscience programs on the NIH campus.

ADVANCING RESEARCH ON NATURAL PRODUCTS

NCCAM remains strongly committed to developing better evidence and information resources on the safety and efficacy of commonly used natural products. The Center is targeting investment in research in this arena on understanding the biological mechanisms of these products, thus creating the translational foundation for subsequent human studies.

In addition, research examining issues of safety is of great public health importance, given the widespread availability and use of these products by the public. In this regard, one area of specific need is rigorous scientific information about interactions of these products with drugs or with other natural products. This spring, NCCAM will lead a workshop, cosponsored by the NIH Office of Dietary Supplements and the National Cancer Institute, with researchers from a variety of fields to discuss ways to improve the methodologies needed to study herb-drug interactions. Workshop recommendations will help guide NCCAM's research agenda.

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[27] Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, Institute of Medicine, June 2011.

BUILDING AND DISSEMINATING RIGOROUS EVIDENCE

Researchers studying the effectiveness and safety of health care approaches already in widespread use face methodological challenges, challenges that are not unique to NCCAM's mission. To develop better methods of studying health outcomes in real-world settings, NCCAM is leading an NIH Common Fund initiative, the Health Care Systems Research Collaboratory. The Collaboratory will develop innovative research partnerships with health care delivery organizations to maximize the potential use of electronic health information. NCCAM is also exploring possible collaborations with the DOD and the VA, aiming to leverage the data being gathered on the use of complementary and integrative practices in their health care systems. Additionally, NCCAM is providing leadership and support to the trans-NIH Patient-Reported Outcomes Measurement Information System (PROMIS), which will provide clinicians and researchers with more efficient and reliable means for gathering data on a variety of patient-reported measures of health and well-being.

NCCAM continues to provide reliable, objective, and evidence-based information on the usefulness and safety of complementary health practices to the public and health care providers. For example, NCCAM publishes the *Clinical Digest* (nccam.nih.gov/health/providers/digest), a monthly e-newsletter that summarizes the state of the science on complementary health practices and clinical guidelines. Additionally, NCCAM provides an online resource (nccam.nih.gov/health/providers) that enables health care providers to make informed recommendations.

CONCLUSION

Strong consumer use of complementary health practices, and growing integration of these practices into a variety of conventional health care settings are important trends in U.S. health care. While there is emerging evidence of promise for some, there are many important unanswered questions about effectiveness and safety. NCCAM remains committed to building the scientific evidence needed by consumers, providers, and health policy makers to make informed decisions about the use of complementary and integrative health practices.

Josephine P. Briggs, M.D.
Director, National Center for Complementary and Alternative Medicine

Josephine P. Briggs, M.D., an accomplished researcher and physician, is Director of the National Center for Complementary and Alternative Medicine, and Acting Director of the Division of Clinical Innovation at the National Center for Advancing Translational Sciences. Dr. Briggs brings a focus on translational research to the study of complementary health practices to help build a fuller understanding of the usefulness and safety of complementary health practices.

Dr. Briggs received her A.B. *cum laude* in biology from Harvard-Radcliffe College and her M.D. from Harvard Medical School. She completed her residency training in internal medicine and nephrology at the Mount Sinai School of Medicine, New York, where she was also chief resident in the Department of Internal Medicine and a fellow in clinical nephrology. She then held a research fellowship in physiology at Yale School of Medicine, New Haven. Dr. Briggs was a research scientist for 7 years at the Physiology Institute at the University of Munich, Germany.

In 1985, Dr. Briggs moved to the University of Michigan, Ann Arbor, where she held several academic positions, including associate chair for research in the Department of Internal Medicine and professorships in the Division of Nephrology, Department of Internal Medicine and the Department of Physiology. Dr. Briggs joined NIH in 1997 as director of the Division of Kidney, Urologic, and Hematologic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) where she oversaw extramural research activities. While at NIDDK, she co-chaired an NIH Roadmap Committee on Translational Core Resources. In 2006, she accepted a position as senior scientific officer at the Howard Hughes Medical Institute. In 2008, she became NCCAM's second director.

Dr. Briggs's research interests include the renin-angiotensin system, diabetic nephropathy, circadian regulation of blood pressure, and the effect of antioxidants in kidney disease. She has published more than 175 research articles, book chapters, and scholarly publications. Dr. Briggs also has served on the editorial boards of several journals (including the *Journal of Laboratory and Clinical Medicine*, *Seminars in Nephrology*, and *Hypertension*) and was deputy editor for the *Journal of Clinical Investigation*. She is an elected member of the American Association of Physicians and the American Society of Clinical Investigation and a fellow of the American Association for the Advancement of Science. She is a recipient of many awards and prizes, including the Volhard Prize of the German Nephrological Society, the Alexander von Humboldt Scientific Exchange Award, and NIH Director's Awards for her role in the development of the Trans-NIH Type I Diabetes Strategic Plan and her leadership of the Trans-NIH Zebrafish committee. Dr. Briggs is also a member of the NIH Steering Committee, the senior most governing board at NIH.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

John Ruffin, Ph.D.
Director, National Institute on Minority Health and Health Disparities

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute on Minority Health and Health Disparities (NIMHD) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NIMHD budget of $279,389,000 includes an increase of $3,278,000 over the comparable FY 2012 level of $276,111,000.

INTRODUCTION

Millions of Americans from racial and ethnic minority, rural and low-income populations continue to be burdened by disparities in health status and health care, despite recent scientific and medical advances to improve the quality of health in this nation. Evidence-based research has shown that these disparities result from the interaction of multiple chronic influences, such as social, environmental, behavioral, and biological factors. Traditionally, research emphasis has been on examining the biology of health disparities. In recent years, the impact of social factors has become more evident in having a strong causal linkage to health disparities. For example, the role of the social and physical environment, the effect of poor housing circumstances, and the difficulties of accessing transportation to obtain timely needed medical care, are all important factors. Therefore, the elimination of health disparities requires a coordinated and integrated approach across multiple disciplines to understand and solve the underlying biological and non-biological evolution of health disparities. The National Institute on Minority Health and Health Disparities (NIMHD) has been at the forefront leading scientific research and building bridges to eliminate health disparities while working with public and private sector partners.

INNOVATION IN RESEARCH

NIMHD administers a portfolio of programs aimed at approaching health disparities from many angles, embodied in the principal goals of research, research capacity building, and outreach. Through research, the NIMHD seeks to understand the development and progression of diseases and conditions disproportionately affecting underserved populations, and to develop evidence-based strategies to improve prevention, diagnosis, and treatment methods. The Centers of Excellence (COE) Program continues to be a powerful force for encouraging large-scale, transdisciplinary research. COE researchers have analyzed associations between insulin resistance and other markers of disease in a sample of Mexican American adolescents from a severely

disadvantaged community on the Texas-Mexico border. This study found that approximately 50 percent of their sample (mean age, 16 y) were overweight or obese, and more participants were obese than overweight. Participants (27%) in this sample had insulin resistance, a strong predictor of diabetes, and two biomarkers, low high-density lipoprotcin cholesterol and high waist circumference, were strongly linked to insulin resistance. These findings emphasize the need to address insulin resistance at least as early as adolescence to prevent adverse economic, social, and health consequences. Another group found evidence that supports the hypothesis that the loss of function of a molecule that promotes cell adhesion contributes to the development of the aggressive breast cancer commonly found in African American women. NIMHD COE researchers have also discovered that moral beliefs and lack of awareness contribute to low rates of cervical cancer screening in young Asian Amcrican women.

TOWARDS DIVERSITY IN THE WORKFORCE

Building the capacity of individuals, institutions, and communities to conduct research and undertake training, with the goal of strengthening the diversity of the science and medical workforce, are crucial to improving the quality of healthcare of America's underserved populations. The Research Endowment, Research Centers in Minority Institutions (RCMI), and the Building Research Infrastructure and Capacity (BRIC) Programs are the pillar of the NIMHD support for building a national enterprise of academic institutions with the physical and intellectual capability to be leaders in health disparities research. At the University of Texas Brownsville, NIMHD funding has helped to leverage resources for the creation of a new college, the College of Biomedical Sciences and Health Professions, and establish a new degree program in biomedical sciences.

NIMHD continues to recruit an average of 250 new candidates into its Loan Repayment Program annually, adding to the diversity of individuals from health disparity populations in the science and health professions workforce. Many of these scholars are engaged in behavioral, social sciences, prevention, health services, and community-oriented research exploring the various social determinants of health. Some of the innovative research projects include studying text messaging to improve depression treatment adherence in low-income patients, creating web-based treatment programs for substance use in American Indian and Alaska Natives, and examining how perceived discrimination and health system distrust affect behavior and decision-making related to cervical cancer prevention in rural and minority women.

ENGAGING COMMUNITIES

Harnessing the power and insights of diverse communities is another important factor because health disparity populations often encounter cultural or environmental barriers to improved health. Outreach efforts remain at the core of the NIMHD's commitment to engage communities in the research process, and equally important, to translate research findings into culturally and linguistically appropriate tools and programs to educate and empower affected communities and their health care providers.

The Community-Based Participatory Research (CBPR) Initiative supports research that engages communities in the research process as equal partners with scientists. This engagement is valuable in helping communities sustain healthy behaviors over the long-term. For example, one project at Wake Forest University trained members of Latino soccer teams in North Carolina to discuss HIV-prevention behaviors with fellow players. After eighteen months, men in the intervention group were significantly more likely to report consistent condom use and HIV testing than those in a control group. Grantees at Saint Louis University are increasing fruit and vegetable consumption by local black men by producing community gardens. These plots have provided more than 1,800 pounds of fresh produce to 150 families, and residents showed decreases in hypertension and body mass index.

A FUTURE OF SUSTAINABLE COMMITMENT

NIMHD seeks to ensure that the investment and progress that has been made towards eliminating health disparities is not lost. It will continue to identify opportunities to sustain effective programs and initiatives by forging and strengthening partnerships across all sectors, while accelerating the pace of research, policy, practice, and community interventions to address pervasive barriers and emerging issues impeding the elimination of health disparities. It will also be imperative to establish an effective system of coordination for these inter and intra-agency activities. Enhanced understanding of the social determinants of health and how where we live, work, and play influence health outcomes are among the priorities that must be aggressively advanced through innovative approaches. While the issues are many, NIMHD is confident that the infrastructure it has built throughout the Nation is up to the challenge, and it is poised to support and create sustainable interventions that will move the country closer to eliminating health disparities. Ensuring that all Americans have an equal chance at healthy life is not an option. NIMHD remains committed to achieving health equity for underserved communities.

John Ruffin, Ph.D.
Director, National Institute on Minority Health and Health Disparities

Dr. John Ruffin is the Director of the National Institute on Minority Health and Health Disparities (NIMHD). He is the Federal official responsible for minority health and health disparities research activities of the National Institutes of Health (NIH) which constitutes an annual budget of approximately $2.8 billion. He is a well-respected leader and visionary in the field of minority health and health disparities, who has devoted his professional career to improving the health status of racial and ethnic minorities and other medically underserved populations. He has an impressive track record of developing and supporting programs to increase the cadre of minority scientists, physicians, and other health professionals, as well as attract a diverse group of researchers to the health disparities field.

His success has been due in large part to his ability to motivate others and gain the support of key individuals and organizations, as well as to his expertise in strategic planning, administration, and the development of numerous collaborative partnerships. Over his more than 20 year career at the NIH, he has led the transformation of the NIH minority health and health disparities research agenda from a programmatic concept to an institutional reality. Under his leadership the NIH Office of Minority Programs was established to address the health of minorities around the country before transitioning to the Office of Research on Minority Health, and later the National Center on Minority Health and Health Disparities in 2000, as a result of congressional legislation. In March 2010, the Affordable Care Act re-designated the NCMHD to the National Institute on Minority Health and Health Disparities.

Dr. Ruffin has developed the largest biomedical research program in the nation to promote minority health and other health disparities research and training, through multi-faceted collaborations. In his quest to eliminate health disparities, the hallmark of his approach is to foster and expand strategic partnerships in alliance with the NIH Institutes and Centers, various Federal and state agencies, community organizations, academic institutions, private sector leaders, and international governments and non-governmental organizations. Under his leadership, the NIH convened the first national summit on health disparities "The NIH Science of Eliminating Health Disparities Summit" in December 2008 with more than 4,000 individuals from around the world representing various disciplines and sectors. His life-long commitment to academic excellence, improving minority health and promoting training and health disparities research, has earned him distinguished national awards.

Dr. Ruffin received a B.S. in Biology from Dillard University, a M.S. in Biology from Atlanta University, a Ph.D. in Systematic and Developmental Biology from Kansas State University, and completed post-doctoral studies in biology at Harvard University. He has received an honorary doctor of science degree from Spelman College, Tuskegee University, the University of Massachusetts in Boston, North Carolina State University, Morehouse School of Medicine, Meharry Medical College, Tulane University and Dillard University. He has been recognized by various professional, non-profit, and advocacy

organizations including: the National Medical Association, the Society for the Advancement of Chicanos and Native Americans in Science; the Association of American Indian Physicians, the Hispanic Association of Colleges and Universities; the Society of Black Academic Surgeons; and the National Science Foundation. The John Ruffin Scholarship Program is an honor symbolic of his legacy for academic excellence bestowed by the Duke University Talent Identification Program. He has also received the Martin Luther King Jr., Legacy Award for National Service, the Yale University Edward A. Bouchet Leadership Award, and the Samuel L. Kountz Award for his significant contribution to increasing minority access to organ and tissue transplantation; the NIH Director's Award; the National Hispanic Leadership Award; Beta Beta Beta Biological Honor Society Award; the Department of Health and Human Services' Special Recognition Award; and the U.S. Presidential Merit Award.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Roger I. Glass, M.D., Ph.D.
Director, Fogarty International Center

Mr. Chairman and Members of the Committee,

I am pleased to present the President's budget request for the Fogarty International Center (FIC) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 FIC budget of $69,758,000 includes an increase of $219,000 over the comparable FY 2012 level of $69,539,000.

These are exciting times for global health. New HIV prevention strategies and the use of mobile technologies to extend the reach of health interventions are just two examples of research into emerging opportunities that can transform our efforts to improve health around the world. These are also examples of advances that can make a significant impact on health here at home as well as abroad. As populations in both the developed and developing world are vulnerable to existing and emerging infectious agents, as well as the growing non-communicable disease (NCD) epidemic, there is no longer a "them" in global health, only an "us" (Global Health Council).

To most effectively address this shared burden of disease, U.S. scientists can only benefit from the unique insights and collaboration of skilled research partners around the world. At the National Institutes of Health (NIH) and within the U.S. Government, the Fogarty International Center plays a unique role by supporting the development of global health research expertise in the U.S. and abroad, and by fostering the international partnerships that extend the frontiers of science, accelerate discovery, and enable the U.S. to continue to lead in addressing the world's most pressing health challenges.

STRENGTHENING SUSTAINABLE RESEARCH CAPACITY

For over two decades, Fogarty has supported the long-term training of thousands of scientists worldwide. These scientists provide unique insights and perspectives on how to best combat global health challenges, and often contribute to groundbreaking research advances in collaboration with U.S. partners.

As the largest international commitment by any one country to fight a specific disease, the President's Emergency Plan for AIDS Relief (PEPFAR) relies on trained scientists to provide an evidence base for the new and effective strategies that have enabled PEPFAR programs and policies to make significant contributions to the progress towards an AIDS-free generation. For example, with support from Fogarty's longstanding HIV/AIDS research training program, Fogarty-supported researchers have

provided evidence that a new, simpler, and shorter treatment regimen of antibiotics can prevent those infected with the TB bacterium – particularly those who also have HIV – from developing full blown TB. In addition, Fogarty-supported researchers and trainees have also helped demonstrate: the effectiveness of anti-retroviral therapies in stopping mother-to-child transmission of the HIV virus; that male circumcision reduces HIV transmission to HIV-negative female partners; and a reduction in HIV transmission among women using microbicides that incorporate anti-retrovirals.

In response to the increased global burden of non-communicable diseases, Fogarty's NCD-Lifespan research training program supports partnerships between U.S. and low- and middle-income country (LMIC) institutions to build non-communicable diseases research capacity. By focusing on early childhood exposures and the genetic, environmental, and lifestyle risk factors that can contribute to later onset of disease, NCD-Lifespan projects are creating a cadre of investigators and institutions able to conduct research relevant to local and global epidemics in areas such as cancer, stroke, mental illness, and metabolic disorders. In Ghana, for example, Fogarty is supporting the development of a Cardiovascular Research Training Institute as a partnership between New York University and the University of Ghana, to train investigators to conduct research on preventing and treating hypertension, diabetes, stroke, and chronic kidney disease. The resulting cadre of investigators will contribute research and expertise to the global effort to reduce cardiovascular disease morbidity and mortality.

With respect to identification of innovative, sustainable and cost-effective strategies to fulfill its mission, Fogarty recognizes that information and communication technologies, mobile technologies, and distance learning can transform the way in which health and health research training can be conducted in the 21st century - particularly in resource-poor and remote settings. Over 50 Fogarty-supported projects have incorporated distance learning activities, which provide an innovative and cost effective way to connect health research students in the developing world with state-of the-art content on the other side of the globe.

NEWINVESTIGATORS, NEW IDEAS

Over the last decade, American university campuses have seen a soaring interest in global health among students and faculty from diverse fields, placing U.S. universities in an excellent position to help generate solutions to complex global health challenges. Fogarty's International Clinical Research Scholars and Fellows program and International Research Scientist Development Awards capitalize on this groundswell of interest to invest in future American leaders in global health research. These programs are investing in the next generation of talented American scientists, who will develop the skills and sensitivities to conduct research in international settings, and engage talented local researchers who can help to address complex health challenges that affect populations in the U.S. and abroad. Former Scholars and Fellows have developed innovative solutions to concrete global health problems. For example, in Zambia, Dr. Krista Pfaendler developed and implemented an effective and low-cost cervical cancer

screening program using digital cameras for cervical photography and acetic acid (vinegar) for visual inspection.

In 2010, Fogarty piloted a one-year program to support postdoctoral investigators in U.S. universities to carry out innovative, multidisciplinary team research in global health. With support from this program, scientists developed point-of-care telemedicine units built with $2 microscopes that can be attached to a cell phone, enabling diagnosis of infectious diseases, such as malaria and HIV, in remote settings. Because of their ease of use, effectiveness, cost-effectiveness, and the ability for quick diagnosis, these microscopes have the potential to revolutionize care in resource-poor settings. The next generation of this program, Framework Innovations, will support U.S. and developing country institutions as they develop interdisciplinary postdoctoral research training programs in global health and enable young investigators to develop and test concrete and innovative health products, processes, and policies that respond practically and cost-effectively to critical health needs.

ADVANCING TRANSLATIONAL SCIENCE

Innovative strategies are needed to translate biomedical discoveries into new therapies, diagnostics, and prevention tools. Supported by Fogarty's International Cooperative Biodiversity Groups Program, U.S. and international scientists conduct discovery research on potential health applications of molecules—from plants, animals, and microorganisms—and initiate partnerships with companies interested in developing these molecules for potential new drugs or diagnostics. This public-private partnership model has led to four active patents in the areas of cancer, parasitic diseases, and malaria.

CONCLUSION

As the world continues to become more interdependent, international scientific partnerships will play a critical role in building bridges between countries and scientists in the interest of advancing the health of our country and our globe. Fogarty invests in the best and brightest minds and catalyzes long-term, productive research collaborations. Working in partnership with the rest of the NIH, Fogarty's unique programs will continue to push the frontiers of science and enable scientists in the U.S. and abroad to work together to successfully tackle the world's most pressing and complex health challenges.

Roger I. Glass, M.D., Ph.D.
Director, Fogarty International Center

Dr. Glass was named Director of the Fogarty International Center and Associate Director for International Research by NIH Director Elias A. Zerhouni, M.D., on March 31, 2006.

Dr. Glass graduated from Harvard College in 1967, received a Fulbright Fellowship to study at the University of Buenos Aires in 1967, and received his M.D. from Harvard Medical School and his M.P.H. from the Harvard School of Public Health in 1972. He joined the Centers for Disease Control and Prevention in 1977 as a medical officer assigned to the Environmental Hazards Branch. He was a Scientist at the International Center for Diarrheal Disease Research in Bangladesh from 1979-1983 and returned to Sweden where he received his doctorate from the University of Goteborg. In 1984, he joined the National Institutes of Health Laboratory of Infectious Diseases, where he worked on the molecular biology of rotavirus. In 1986, Dr. Glass returned to the CDC to become Chief of the Viral Gastroenteritis Unit at the National Center for Infectious Diseases.

Dr. Glass's research interests are in the prevention of gastroenteritis from rotaviruses and noroviruses through the application of novel scientific research. He has maintained field studies in India, Bangladesh, Brazil, Mexico, Israel, Russia, Vietnam, China and elsewhere. His research has been targeted toward epidemiologic studies to anticipate the introduction of rotavirus vaccines. He is fluent and often lectures in five languages.

Dr. Glass has received numerous awards including the prestigious Charles C. Shepard Lifetime Scientific Achievement Award presented by the CDC in recognition of his 30-year career of scientific research application and leadership, the Dr. Charles Merieux Award from the National Foundation for Infectious Diseases for his work on rotavirus vaccines in the developing world and the Programme for Global Paediatric Research Award for Outstanding Contributions to Global Child Health. He is a member of the Institute of Medicine of the U.S. National Academies of Science.

Dr. Glass has co-authored more than 500 research papers and chapters. He is married to Barbara Stoll, M.D., the George W. Brumley, Jr. Professor and Chair of the Department of Pediatrics at Emory University School of Medicine and the Medical Director of the Children's Healthcare of Atlanta at Egleston. He and his wife have three children.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Donald A.B. Lindberg M.D.
Director, National Library of Medicine

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Library of Medicine (NLM) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 NLM budget of $372,651,000 includes an increase of $7,608,000 over the comparable FY 2012 level of $365,043,000. Funds have been included to allow the National Center for Biotechnology Information (NCBI) to meet the challenges of collecting, organizing, analyzing, and disseminating the deluge of data emanating from research in molecular biology and genomics.

As the world's largest biomedical library and the producer of internationally trusted electronic information services, NLM delivers trillions of bytes of scientific data and health information to millions of users every day. Many searches that begin in Google or a mobile "app" actually retrieve information from an NLM website. After 175 years, NLM is a key link in the chain that makes biomedical research results—DNA sequences, clinical trials data, toxicology and environmental health data, published articles, and consumer health information—readily available to scientists, health professionals, and the public. A leader in biomedical informatics and information technology, NLM also conducts and supports leading-edge research and development in electronic health records, clinical decision support, information retrieval, imaging, computational biology, telecommunications, and disaster response.

NLM's programs and services directly support NIH's four key initiatives in basic research, technology, translational science, and research training. The Library organizes and provides access to the published medical literature and massive amounts of scientific data from high throughput sequencing; assembles data about small molecules to support research and therapeutic discovery; provides the world's largest clinical trials registry and results database; and is the definitive source of published evidence for health care decisions. Research supported or conducted by NLM underpins today's electronic health record systems. The Library has been the principal funder of university-based informatics research training for 40 years, supporting the development of today's leaders in informatics research and health information technology. NLM's databases and its partnership with the nation's health sciences libraries deliver research results wherever they can fuel discovery and support health decision-making.

RESEARCH INFORMATION RESOURCES

NLM's PubMed/MEDLINE database is the world's gateway to research results published in the biomedical literature, linking to full-text articles in PubMed Central, including those deposited under the NIH Public Access Policy, and on publishers' websites, as well as connecting to vast collections of scientific data. Through its National Center for Biotechnology Information (NCBI), NLM is a hub for the international exchange and use of molecular biology and genomic information, with many databases fundamental to the identification of important associations between genes and disease and to the translation of new knowledge into better diagnoses and treatments. Resources such as dbGaP, the Genetic Testing Registry (GTR) and the ClinVar database create a bridge between basic research and clinical applications.

NLM also stands at the center of international exchange of data about clinical research studies. NLM's Lister Hill National Center for Biomedical Communications builds ClinicalTrials.gov, the world's most comprehensive clinical trials database, including registration data for more than 117,000 clinical studies with sites in 178 countries. ClinicalTrials.gov has novel and flexible mechanisms that enable submission of summary results data for clinical trials subject to the Food and Drug Administration Amendments Act of 2007. To date, summary results are available for more than 5,000 completed trials of FDA-approved drugs, biological products, and devices – providing a new and growing source of evidence on efficacy and comparative effectiveness. NLM is a primary source for results of comparative effectiveness research, providing access to evidence on best practices to improve patient safety and health care quality. In 2011, the Library greatly expanded its collection of full-text guidelines, evidence summaries, and systematic reviews from authoritative agencies and organizations around the world.

HEALTH DATA STANDARDS AND ELECTRONIC HEALTH RECORDS

Electronic health records (EHRs) with advanced decision-support capabilities and connections to relevant health information will be essential to achieving precision medicine and helping Americans manage their own health. For 40 years, NLM has supported seminal research on electronic patient records, clinical decision support, and health information exchange, including concepts and methods now reflected in EHR products and personal health record tools, such as Microsoft Health Vault. As the HHS coordinating body for clinical terminology standards, NLM works closely with the Office of the National Coordinator for Health Information Technology to facilitate adoption and "meaningful use" of EHRs. NLM supports, develops, and disseminates several key data standards now required for U.S. health information exchange. While actively engaged in research on Next Generation EHRs, NLM also produces tools, frequently used subsets of large terminologies, and mappings to help EHR developers and users implement health data standards right now. NLM's MedlinePlus Connect is used in multiple EHR products to provide high quality health information relevant to a patient's specific health conditions, medications, and tests, as present in his or her EHR.

INFORMATION SERVICES FOR THE PUBLIC

This EHR connection builds upon NLM's extensive information services for patients, families and the public. The Library's MedlinePlus website provides integrated access to high quality consumer health information produced by all NIH components and HHS agencies, other federal departments, and authoritative private organizations. It serves as a gateway to specialized NLM information sources for consumers, such as the Genetic Home Reference and the Household Products Database. Available in English and Spanish, with selected information in 40 other languages, MedlinePlus averages well over 750,000 visits per day. Mobile MedlinePlus, also in both English and Spanish, reaches the large and rapidly growing mobile Internet audience.

The *NIH MedlinePlus* magazine, in English and Spanish, is an outreach effort made possible with support from many parts of NIH and the Friends of the NLM. Distributed free to the public via physician offices, community health centers, libraries and other locations, the magazine reaches a readership of up to 5 million nationwide. Each issue focuses on the latest research results, clinical trials and guidelines from the 27 NIH Institutes and Centers.

To be of greatest use to the widest audience, NLM's information services must be known and readily accessible. The Library's outreach program, with a special emphasis on reaching underserved populations, relies heavily on the more than 6,300-member National Network of Libraries of Medicine (NN/LM). The NN/LM is a network of academic health sciences libraries, hospital libraries, public libraries and community-based organizations working to bring the message about NLM's free, high-quality health information resources to communities across the nation.

DISASTER INFORMATION MANAGEMENT

Through its Disaster Information Management Resource Center, NLM builds on proven emergency backup and response mechanisms within the NN/LM to promote effective use of libraries and information specialists in disaster preparedness and response. NLM conducts research on new methods for sharing health information in emergencies as its contribution to the Bethesda Hospital Emergency Preparedness Partnership, a model of private-public hospital collaboration for coordinated disaster planning. NLM works with the Pan American Health Organization (PAHO) and the Latin American Network for Disaster and Health Information to promote capacity-building in disaster information management. In addition, NLM responds to specific disasters worldwide with specialized information resources appropriate to the need, including a recently launched Disaster Information Apps and Mobile Web Sites page.

In summary, NLM's information services and research programs serve the nation and the world by supporting scientific discovery, clinical research, education, health care delivery, public health response, and the empowerment of people to improve personal health. The Library is committed to the innovative use of computing and communications to enhance public access to the results of biomedical research.

Donald A.B. Lindberg M.D.
Director, National Library of Medicine

Donald A.B. Lindberg, M.D., a scientist who pioneered applying computer technology to health care beginning in 1960, was appointed Director of the National Library of Medicine in 1984. From 1992-1995, he concurrently served as the Director of the President's Initiative on High Performance Computing and Communications (HPCC). In 1996, he was named by the HHS Secretary to be the U.S. Coordinator for the G-7 Global Health Applications Project.

In addition to an eminent career in pathology, Dr. Lindberg has made notable contributions to information and computer activities in medical diagnosis, artificial intelligence, and educational programs. Before his appointment as NLM Director, he was Professor of Information Science and Professor of Pathology at the University of Missouri-Columbia.

Dr. Lindberg was elected the first President of the American Medical Informatics Association (AMIA). As the country's senior statesman for medicine and computers, he has been called upon to serve on many boards including the Computer Science and Engineering Board of the National Academy of Sciences, the National Board of Medical Examiners, and the Council of the Institute of Medicine of the National Academy of Sciences.

Dr. Lindberg is the author of three books: The Computer and Medical Care, Computers in Life Science Research, and The Growth of Medical Information Systems in the United States; numerous book chapters; and more than 200 articles and reports. He has received many awards, including the Presidential Senior Executive Rank Award, two U.S. Surgeon General's medallions, the American Medical Association's Nathan Davis Award for Outstanding Member of the Executive Branch.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director, National Institutes of Health

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the Office of the Director (OD) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2013 OD budget of $1,429,161,000 includes a decrease of $28,220,000 below the comparable FY 2012 level of $1,457,381,000.

The OD promotes and fosters NIH research and research training efforts in the prevention and treatment of disease through the policy oversight of both the extramural grant and contract award functions and the Intramural Research program. The OD stimulates specific areas of research to complement the ongoing efforts of the Institutes and Centers through the activities of several cross-cutting program offices. The OD also develops policies in response to emerging scientific opportunities employing ethical and legal considerations; provides oversight of peer review policies; coordinates information technology across the Agency; and, coordinates the communication of health information to the public and scientific communities.

The FY 2013 request will also support activities managed by the OD's operational offices. OD Operations is comprised of several OD Offices that provide advice to the NIH Director, policy direction and oversight to the NIH research community and administer centralized support services essential to the NIH mission.

The functions and initiatives of the OD's research offices, also known as Program, Projects and Activities, are described in detail as follows:

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI)

DPCPSI is the home for cross-cutting offices that support research in areas of emerging scientific opportunity, rising public health challenges, or knowledge gaps that deserve special emphasis. DPCPSI's scope expanded in FY 2012 with the creation of a new Office of Research Infrastructure Programs (ORIP) which supports research resources that serve grantees across the NIH. In addition to ORIP, there are five offices that are described below. The FY 2013 budget for DPCPSI, Office of the Director and the Office of Strategic Coordination is $8,116,000.

OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

ORIP supports research infrastructure, research-related programs, and NIH's science education efforts. Within ORIP, the Division of Comparative Medicine provides scientists with essential resources—including specialized disease-model laboratory animals, research facilities, training, and other tools—that enable research funded by all NIH ICs. The Shared and High End Instrumentation programs provide support for the purchase of research equipment, ranging in cost from $100,000 to $2,000,000. The Animal Facilities Improvement program provides funds to modernize animal facilities that support biomedical and behavioral research. ORIP also currently monitors more than 350 construction awards that have not yet reached their 20-year milestone and 147 ARRA awards for 10 years. The ORIP budget for FY 2013 is $283,698,000. The Science Education Partnership Awards (SEPA) program encourages pre K-12 projects that support diversity in the research workforce as well as museum exhibits for students, teachers, and the public. In FY 2013, the budget for SEPAs is $20,282,000. The Office of Science Education (OSE) develops science education programs, instructional materials, and career resources that serve our nation's science teachers, their students, and the public. The FY 2013 budget for OSE is $3,980,000.

THE OFFICE OF AIDS RESEARCH (OAR)

OAR plays a unique role at NIH, establishing a plan for the AIDS research program. OAR coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. OAR's response to the AIDS epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. The FY 2013 budget for OAR is $63,802,000.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH (OBSSR)

OBSSR was established by Congress to stimulate behavioral and social science research at NIH and to integrate it more fully into the NIH research enterprise. To address the contribution of behavior to health and disease, OBSSR supports the activities of the NIH Basic Behavioral and Social Science Opportunity Network, a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research. The FY 2013 budget for OBSSR is $27,001,000.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH (ORWH)

The mission of ORWH is to advance NIH research on women's health. This is accomplished by catalyzing innovative research addressing the gaps in knowledge

regarding diseases and conditions that affect women and in partnership with the ICs through the implementation of the NIH strategic plan for women's health and sex differences research which serves as a framework for interdisciplinary scientific approaches. ORWH promotes the recruitment, retention, reentry, and sustained advancement of women in biomedical careers and continues to lead efforts to ensure adherence to policies for the inclusion of women and minorities in NIH clinical research. The FY 2013 budget for ORWH is $42,324,000.

THE OFFICE OF DISEASE PREVENTION (ODP)

The mission of ODP is to foster, coordinate, and assess research in disease prevention and health promotion at the NIH. ODP collaborates with other Federal and international organizations, academic institutions, and the private sector in formulating new research initiatives and policies to improve public health. The FY 2013 budget for ODP is $6,065,000. The Office of Dietary Supplements (ODS) is within the ODP organizational structure. ODS strengthens knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public. The FY 2013 budget for ODS is $27,717,000.

THE OFFICE OF STRATEGIC COORDINATION (OSC) AND THE COMMON FUND

OSC leads strategic planning for and centrally manages Common Fund (CF)-supported programs. OSC works with staff across the NIH in CF program development and implementation. The NIH CF was created by the 2006 NIH Reform Act which codified the approach of the NIH Roadmap for Medical Research to support cross-cutting, trans-NIH programs that require participation by at least two NIH ICs or would otherwise benefit from strategic planning and coordination. The CF provides limited-term funding for goal-driven, coordinated research networks to generate data, solve technological problems, and/or pilot resources and tools that will stimulate the broader research community. The FY 2013 budget for the Common Fund is $544,930,000.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAMS

The NIH Intramural Loan Repayment Programs seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees. These programs offer financial incentives and other benefits to attract highly qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of the NIH. The Undergraduate Scholarship Programs (UGSP) offers competitive scholarships to exceptional college students from disadvantaged backgrounds that are committed to biomedical, behavioral, and social science health-related research careers at the NIH. The FY 2013 budget for ILRSP is $7,393,000.

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director, National Institutes of Health

Dr. Tabak was appointed as the principal deputy director of the NIH on August 23, 2010. Previously he served as acting principal deputy director of the NIH from November 13, 2008 through August 14, 2009. Named as the director of the National Institute of Dental and Craniofacial Research (NIDCR) in September 2000, he held that post through August 2010.

Dr. Tabak has served as co-chair of several trans-NIH activities, including the NIH-wide initiative to enhance peer-review. While serving as the NIH acting deputy director in 2009, Dr. Tabak played a leadership role in coordinating the agency's response to the American Recovery and Reinvestment Act.

Prior to joining NIH, Dr. Tabak was the senior associate dean for research and professor of dentistry and biochemistry & biophysics in the School of Medicine and Dentistry at the University of Rochester in New York. A former NIH MERIT recipient, Dr. Tabak's major research focus has been on glycoprotein biosynthesis and function. He continues to lead an active research laboratory within the NIH intramural program in addition to his administrative duties.

Dr. Tabak is a fellow of the AAAS and a member of the Institute of Medicine of the National Academies. A native of Brooklyn, New York, he received his undergraduate degree from City College of the City University of New York, his D.D.S. from Columbia University, and a Ph.D. from the University of Buffalo.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Statement for the Record

Jack E. Whitescarver, Ph.D.
Director, Office of AIDS Research
Associate Director, AIDS Research

Mr. Chairman and Members of the Committee:

I am pleased to present the Fiscal Year (FY) 2013 President's budget request for the trans-NIH AIDS research program, which is $3,074,921,000. This amount is the same as the FY 2012 Enacted level. It includes the total trans-NIH support for intramural and extramural research for basic, clinical, behavioral, social science, and translational research on HIV/AIDS and the wide spectrum of AIDS-associated malignancies, opportunistic infections, co-infections, and clinical complications; as well as research management support; research centers; and training.

Within the total, the Office of AIDS Research (OAR) has provided increases to high priority prevention research in the areas of microbicides, vaccines, behavioral and social science, and treatment as prevention research, as well as to etiology and pathogenesis research that provides the essential basic science foundation not only for AIDS-related research but for other related diseases and conditions as well. In order to provide those increases, OAR has reduced and redirected funds from other areas, including natural history and epidemiology, therapeutics, and training and infrastructure support.

THE AIDS PANDEMIC

The HIV/AIDS epidemic continues to expand. UNAIDS estimates that in 2010, more than 34 million people were living with HIV/AIDS; 2.7 million were newly infected; and 1.8 million people died of AIDS-related illnesses. In the United States, CDC estimates that more than 1.2 million people are HIV-infected; and someone is infected with HIV every 9-and-a-half minutes. AIDS disproportionately affects racial and ethnic populations, women of color, young adults, and men who have sex with men. The number of individuals aged 50 years and older living with HIV/AIDS is increasing, due in part to antiretroviral therapy, which has made it possible for many HIV-infected persons to live longer, but also due to new infections in individuals over the age of 50. The AIDS pandemic has devastating consequences around the world in virtually every sector of society. Further research to improve prevention and treatment is urgently needed. Advances in prevention and treatment also will have extensive economic benefits.

30 YEARS OF EXTRAORDINARY NIH AIDS RESEARCH ACCOMPLISHMENTS

HIV, the virus that causes AIDS, is one of the most complex pathogens to affect human health and challenge biomedical research. In the three decades since AIDS was first recognized, NIH has established the world's leading AIDS research program. This investment in HIV research has transformed the disease from a mysterious and uniformly fatal infection into one that can be accurately diagnosed and effectively managed with appropriate treatment. A recent study estimated that 14.4 million life-years have been gained among adults around the world since 1995 as a result of AIDS therapies developed through NIH-funded research.

NIH research has resulted in landmark advances that have led to:

- the co-discovery of HIV, the virus that causes AIDS;
- development of the first blood test for the disease, which has allowed diagnosis of infection as well as ensured the safety of the blood supply;
- the critical discovery of key targets to develop Antiretroviral Therapies (ART) and multi-drug regimens that have resulted in improved life expectancy for those with access to and who can tolerate these drugs;
- the development of treatments for many HIV-associated coinfections, comorbidities, malignancies, and clinical manifestations, with benefits for patients also suffering from those other diseases;
- groundbreaking strategies for the prevention of mother-to-child transmission, which have resulted in dramatic decreases in perinatal HIV in the United States;
- demonstration that the use of male circumcision can reduce the risk of HIV acquisition;
- the first step in proving the concept that a vaccine to prevent HIV infection is feasible; and discovery of two potent human antibodies that can stop more than 90 percent of known global HIV strains from infecting human cells in the laboratory;
- demonstration of the first proof of concept for the feasibility of a microbicide gel capable of preventing HIV transmission;
- demonstration that the use of therapy by infected individuals can dramatically reduce transmission to an uninfected partner;
- groundbreaking research regarding Pre-Exposure Prophylaxis (PrEP), examining whether the use of antiretroviral treatment regimens by some groups of high-risk uninfected individuals could reduce the risk of HIV acquisition
- discovery that genetic variants may play a role in protecting some individuals, known as "elite controllers," who have been exposed to HIV over an extended period, from developing symptoms and enabling them to control the infection without therapy;
- critical basic science discoveries that continue to provide the foundation for novel research; and
- progress in both basic and treatment research efforts aimed at eliminating viral reservoirs in the body, which is, for the first time, leading scientists to design and conduct research aimed at a cure.

EXTRAORDINARY OPPORTUNITIES FOR FY 2013

Advances made by NIH investigators have opened doors for new and exciting research opportunities to answer key scientific questions that remain in the search for strategies to prevent and treat HIV infection both in the U.S. and around the world, and represent the building blocks for the development of the OAR Trans-NIH AIDS research budget:

- **Investing in Basic Research:** OAR will increase support for basic research that will underpin further development of critically needed ***vaccines and microbicides.***

- **Encouraging New Investigators and New Ideas:** OAR will provide additional support for innovative multi-disciplinary research and international collaborations to develop novel approaches and strategies to eliminate viral reservoirs that could lead toward ***a cure for HIV.***

- **Accelerating Discovery Through Technology:** OAR will increase funds to support critical studies in the area of ***therapeutics as a method to prevent infection***, including treatment to prevent HIV infection after exposure; Pre-Exposure Prophylaxis (PrEP); a potential prevention strategy known as "test and treat," to determine whether a community-wide testing program with treatment can decrease the overall rate of new HIV infections; and improved strategies to prevent mother-to-child transmission. A key priority is to evaluate prevention interventions that can be used in combination in different populations, including adolescents and older individuals.

- **Improving Disease Outcomes:** OAR will target funding for NIH research focused on developing better, less toxic treatments and investigating how genetic determinants, sex, gender, race, age, nutritional status, treatment during pregnancy, and other factors interact to affect treatment success or failure and/or disease progression. Studies will address the increased incidence of malignancies, cardiovascular and metabolic complications, and premature aging associated with long-term HIV disease and ART.

- **Advancing Translational Sciences:** OAR will ensure adequate resources for research on the feasibility, effectiveness, and sustainability required to scale-up interventions from a structured behavioral or clinical study to a broader "real world" setting.

GLOBAL IMPACT OF NIH AIDS RESEARCH

Research to address the global pandemic is essential. AIDS research represents the largest component of the total NIH global research investment. Since the early days of the epidemic, NIH has maintained a strong international AIDS research portfolio that has grown to include projects in approximately 100 countries around the world. NIH AIDS research studies are designed so that the results are relevant for both the host nation and the U.S. These research programs also enhance research infrastructure, and training of in-country scientists and healthcare providers. New collaborations have been designed

to improve both medical and nursing education as a mechanism to build a cadre of global health leaders. Most of these grants and contracts are awarded to U.S.-based investigators to conduct research in collaboration with in-country scientists; some are awarded directly to investigators in international scientific or medical institutions.

BENEFITS OF AIDS RESEARCH TO OTHER DISEASES

It is essential to point out that AIDS research also pays extensive dividends in many other areas of biomedical research, including in the prevention, diagnosis and treatment of many other diseases. It deepens our understanding of immunology, virology, microbiology, molecular biology, and genetics. AIDS research is helping to unravel the mysteries surrounding so many other diseases because of the pace of discovery and because of the unique nature of HIV, i.e., the way the virus enters a cell, causes infection, affects every organ system, and unleashes a myriad of opportunistic infections, co-morbidities, cancers, and other complications. AIDS research continues to make discoveries that can be applied to other infectious, malignant, neurologic, autoimmune, and metabolic diseases, as well as complex issues of aging and dementia, AIDS treatment research has led to more effective drugs for multiple bacterial, mycobacterial, and fungal diseases and fostered significant improvements in drug design technologies. AIDS research has led to the development of new models to test treatments for other diseases in faster, more efficient and more inclusive clinical trials. Drugs developed to prevent and treat AIDS-associated opportunistic infections also now benefit patients undergoing cancer chemotherapy and patients receiving anti-transplant rejection therapy. AIDS research also has advanced understanding of the relationship between viruses and cancer. New investments in AIDS research will continue to fuel biomedical advances and breakthroughs that will have profound benefits far beyond the AIDS pandemic.

SUMMARY

Despite these advances, however, AIDS is not over, and serious challenges lie ahead. The HIV/AIDS pandemic will remain the most serious public health crisis of our time until better, more effective, and affordable prevention and treatment regimens are developed and universally available. NIH will continue to search for solutions to prevent, treat, and eventually cure AIDS.

Jack E. Whitescarver, Ph.D.
Director, Office of AIDS Research
Associate Director, AIDS Research

Dr. Whitescarver received his doctorate in medical microbiology in 1974 from the University of Medicine and Dentistry of New Jersey (UMDNJ), Graduate School of Biomedical Sciences. He pursued his post-doctoral research at the Harvard School of Public Health, focusing on immunopathogenesis of rickettsia infection. In his position as a Research Associate at the Harvard School of Public Health and Medical School, Dr. Whitescarver's research interests included obligate intracellular parasites. His published research results include in vitro studies on breast tumors, spirochetes, mycoplasmas, and rickettsia.

In 1977, Dr. Whitescarver completed a year in the Grants Associates Program at the National Institutes of Health (NIH) and became the Special Assistant to the Director of the National Institute of Allergy and Infectious Diseases (NIAID). In that position he was responsible for assisting the Director in policy, planning and budget issues. It was during this tenure that Dr. Whitescarver first reported to the NIAID on the possibility of the emergence of a new infectious disease, now known as AIDS, and he helped develop the initial federal response for research on AIDS.

From 1984 to 1988, Dr. Whitescarver held the positions of Associate Dean for Research Development and Assistant Professor of Pathology at Emory University School of Medicine. His duties as Associate Dean included directing the M.D. /Ph.D. training program and facilitating new research initiatives, particularly in AIDS.

In 1988, the new Office of AIDS Research (OAR) at the NIH was established, and Dr. Whitescarver was recruited as the Deputy Director. He served as Acting Director of the OAR from October 2000 until June 2002, when he was named permanent Director. Under his leadership, OAR has launched a number of innovative domestic and international initiatives.

Dr. Whitescarver is a member of several professional societies including the American Academy of Allergy and Immunology, Infectious Diseases Society of America, the Royal Society of Medicine, and the International AIDS Society. He has received numerous honors and awards. In 2010, he was awarded the first International AIDS Society (IAS) Presidential Award for his commitment to the global fight against HIV and his pioneering work in the field. He currently serves as Co-Chair with Nobel Laureate Prof. Francoise Barre-Sinoussi of the IAS Advisory Board to develop a scientific strategy towards an HIV cure.

Mr. REHBERG. Again, gentleman, thank you, and the audience as well. Thank you.

Department of Labor, Health and Human Services, and Education, and Related Agencies

FY13 Budget Request Hearing
March 20, 2012

QUESTIONS FOR NIH DIRECTOR TO BE SUBMITTED FOR THE PUBLIC HEARING RECORD

Questions From Chairman Rehberg

1) **In the FY12 Statement of Managers, Congress was clear that we want to see CTSAs maintained to cover the full spectrum of research they now do and that changes should not even be considered once IOM completes an independent evaluation of the CTSAs. - - Please explain the status of the IOM review and timing for completion?**
- Please explain the steps NIH is taking to ensure no changes to the CTSA program are made until the IOM evaluation is competed?
- When will you issue the next round of grants?
- Please provide assurance the next round of grants will maintain the current scope of the CTSA program?

Answer: NCATS is currently working on how to secure the desired report most expeditiously, in response to congressional report language that "the conferees urge NIH to support a study by the IOM that would evaluate the CTSA program and recommend whether changes to the current mission are needed." The Congressional report language calls for this report to be available no later than 18 months after the enactment of the bill, which is June 23, 2013. NIH has been in communication with the IOM. While we do not yet have more information on the status of the review, we fully expect it will be completed by the requested date.

CTSA awards are granted for five years, and every year a new competition is held for continuation of existing awards and competition for new sites. Work on the CTSA FOA is underway, and is expected to be issued in June 2012. We expect grants will be awarded during the summer of 2013. This next round of CTSA grants will maintain the current scope of the CTSA program, but that does not mean no changes to the program will be made in the FOA. As in the past, the CTSA program receives continual stakeholder input to ensure that there are new opportunities to provide optimal results to move basic discoveries into improved human health, and the FOA is the appropriate vehicle for incremental improvements. We look forward to the recommendations from the IOM to help guide the ever-evolving CTSA program. However, NIH cannot halt the upcoming FOA process to await the completion of the IOM report in June 2013.

2) **NIH currently has an RFI pending asking for input from the community of researchers about the new institute. The community has raised concerns that NIH does not intend to make the comments submitted available to the public. Please explain the steps NIH will take to ensure it is maintain transparency? Plus, explain how NIH expects to use this information in light of the impending program review by IOM and restriction to delay any changes until the IOM has completed its evaluation of the CTSA program.**

Answer: The Request for Information (RFI) was in regards to the Clinical and Translational Science Awards (CTSA) Program and its role within NCATS and within the broader research community at large. The RFI was called Enhancing the Clinical and Translational Science Awards (CTSA) Program and responses to the RFI are due on April 6, 2012. Public comment was sought on how NCATS can better structure and position the CTSA program to develop novel designs, methods and research and to enrich the translational pipeline. Over 130 comments were received in response to this RFI, which NIH will make available on its website to the public and to the IOM.

CTSA awards are granted for five years, and every year a new competition is held for continuation of existing awards and competition for new sites. Work on the CTSA FOA is underway, and is expected to be issued in June 2012. We expect grants will be awarded during the summer of 2013. This next round of CTSA grants will maintain the current scope of the CTSA program, but that does not mean no changes to the program will be made in the FOA. As in the past, the CTSA program receives continual stakeholder input to ensure that there are new opportunities to provide optimal results to move basic discoveries into improved human health, and the FOA is the appropriate vehicle for incremental improvements. We look forward to the recommendations from the IOM to help guide the ever-evolving CTSA program. However, NIH cannot halt the upcoming FOA process to await the completion of the IOM report in June 2013.

3) In the FY 12 Statement of Managers, Congress said that what is needed is "full consideration by the SMRB." We understand NIH and the SMRB process is considering more eliminations of Institutes and Centers (ICs) and the creation of a new Addiction Institute. It is important NIH does not attempt to side step the process as NIH did with NCATS.

- **Please provide specific assurance that the SMRB will answer each of the specific questions required by law in its report that included the mission, cost projections, scientific value of the existing ICs and new organization, duplication with other NIH ICs and HHS organizations.**

- **The SMRB statute mandates that it include cost projections for any new initiative. We understand the report does not indicate all the statutory elements are addressed. When do you intend to refer this matter back to the SMRB so that they can meet their statutory mandate?**

- **Please have the SMRB explain how the researcher community been asked to give input on potential costs of this proposal?**

- **Please have the SMRB provide examples of how to combine portfolios from multiple institutes? What economic model NIH should use for budget planning?**

- **Please have the SMRB explain how its reorganization proposals reflect the public health burdens during its review?**

Answer: The role of the SMRB is outlined in Section 401(e)(2)(B) of the PHS Act. That section states that budgetary and operational analyses are to be carried out if the SMRB is giving significant consideration to proposing a recommendation for organizational change. It does not state that the SMRB report itself must contain budgetary and operational analyses.

The SMRB carried out these activities during the course of its year-and-a-half long study of the optimal organization of substance use, abuse, and addiction-related research at NIH; the SMRB worked through each of the analytical factors outlined in the statute. A summary of the SMRB's findings regarding these requirements is provided below:

- *Budgetary and operational consequences.* The SMRB took into account the budgetary issues of its proposed recommendation and concluded that, since programs were being moved from one IC to another rather than being created de novo, the proposed changes were budget neutral. SMRB members acknowledged that operational efficiencies and cost savings may be achieved at some point in the future, but, ultimately, concluded that scientific considerations should drive the discussion of what type of organizational change is needed. In this regard, the Board pointed to important synergies that could be realized by bringing these programs together and noted that there were significant opportunity costs in not organizing them in the most effective manner.
- *Relative historical funding and support for newer and older ICs.* The SMRB consulted with numerous stakeholders regarding the complicated history of drug and alcohol research funding within the Federal government. Extensive consultations were held with current and past directors of both the National Institute for Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse. SMRB members also reviewed historical data from across the various NIH ICs. Data included institutes' appropriations history, success rates, and investment in substance use, abuse, and addiction research.
- *Estimated level of resources needed for implementation.* The SMRB concluded that reorganization would help NIH leverage existing resources and use funds more efficiently through enhanced synergies between addiction-related research areas. The Board found this effect to be particularly compelling in light of the potential for flat budgets at NIH in the near future. Moreover, after reviewing the size and budgets of cross-cutting programs to be included in the new entity, the Board concluded that this shift would be relatively budget-neutral.
- *Allocation of resources among ICs.* During its deliberations, the SMRB reviewed information about the investment in substance use, abuse, and addiction research across NIH. The Board concluded that a number of existing programs at NIH would benefit from stronger functional and/or structural ties; that synergies between these programs are currently not being fully realized; and that a strategic reorganization of addiction-related research programs at NIH should not be delayed.

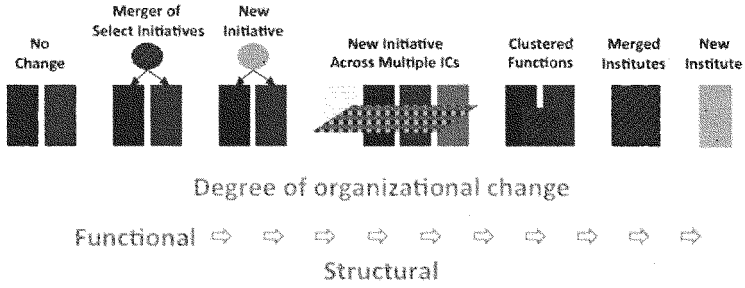
The SMRB *Report on Substance Use, Abuse, and Addiction Research at NIH* describes its process for gathering stakeholder input on the optimal organization of substance use, abuse, and addiction research at NIH. The SMRB consulted with diverse stakeholders throughout the process and held several stakeholder forums to gather input on its process, findings, and recommendations. A full list of consultations is provided below.

In fact, for every topic the SMRB considers, SMRB members undertake an extensive consultation process to ensure that all stakeholders have had ample opportunity to provide input during their deliberations, as well as provide feedback regarding their proposed recommendations. This approach is reflected in each report issued to date (*Report on Deliberating Organizational Change and Effectiveness*, *Report on the NIH Clinical Center*, *Report on Substance Use, Abuse, and Addiction Research at NIH*, and *Report on Translational Medicine and Therapeutics*). As part of its process, the SMRB holds public meetings, which are announced to the public in the Federal Register and on the NIH website. For each topic considered, the Board devotes at least one entire meeting to gathering input specifically from the research community. Stakeholders are also invited to submit written comments to the Board and to make remarks during public comment periods at each SMRB meeting.

A review of the SMRB *Report on Deliberating Organizational Change and Effectiveness* provides insights into how portfolios across institutions can be combined or synergized. SMRB members recognized early in the Board's tenure that to be effective in its consideration of organizational change at NIH, it would need to establish 1) defining criteria for determining when organizational change should be contemplated; 2) guiding principles for the process of deliberation; and 3) appropriate attributes of a process for considering and, if warranted, undertaking organizational change. This framework, outlined

in the SMRB *Report on Deliberating Organizational Change and Effectiveness*, serves as the foundation for the SMRB's process.

As part of this framework, the SMRB developed a spectrum of options, illustrated below, for organizational change that range from the status quo to increasing degrees of functional change to structural change.



For instance, the Board used this tool to consider how to achieve the best scientific synergies across the NIH's substance use, abuse, and addiction related-research portfolio and is detailed in its *Report on Substance Use, Abuse, and Addiction Research at NIH*. In this case, the options identified by the Board were 1) maintaining the status quo; 2) combining National Advisory Councils; 3) merging select portfolios from two ICs; 4) creating a new initiative shared by the research portfolios of two ICs; 5) creating a new initiative across multiple IC research portfolios; 6) clustering functions across IC research portfolios; 7) merging institutes and their respective research portfolios; and 8) creating a new institute with a specific, focused research portfolio. The framework process also involves evaluating the viable change options, conducting risk-benefit analysis of each viable option, soliciting and analyzing key stakeholder perspectives, and identifying and analyzing the broader implications of each option.

NIH has given careful consideration to the SMRB findings and agrees that the current organization of substance use, abuse, and addiction-related research at NIH does not optimally capitalize on existing and potential synergies that could be facilitated within a single Institute. To develop a detailed plan for the reorganization, NIH has convened an internal task force to recommend which existing research portfolios should be included in the new Institute and a planning committee composed of scientific experts to develop a scientific strategic plan. Budget planning will be similar to that of existing Institutes in that it will seek to maintain portfolio balance while pursuing important strategic directions.

A review of the SMRB's work illustrates how its reorganizational proposals reflect the public health. The fundamental premise of the SMRB's mandate, as defined in its *Report on Deliberating Organizational Change and Effectiveness*, is that "any rationale for organizational change at NIH must be to improve the agency's ability to fulfill its mission." Paramount to this mission is to pursue and apply fundamental knowledge to extend healthy life and reduce the burdens of illness and disability.

Throughout each of its analyses, the SMRB carefully assessed both the scientific landscape and the public health needs regarding the topic under consideration. The same is true for the proposal to create a new Institute to advance substance use, abuse, and addiction research at NIH. Stakeholders

emphasized the public health burden of addiction, including the number of Americans directly or indirectly affected by alcohol, drug, and tobacco abuse, as well as gambling addictions, and the age and socioeconomic distribution of those affected. The effect of substance abuse on the U.S. judicial and prison systems was raised by several stakeholders. The status quo was rejected as insufficient for addressing this enormous public health burden, and failure to bring addiction-related research into closer alignment was viewed as an opportunity cost with public health consequences.

SMRB Consultations with Stakeholders in the Development of the SMRB Report on Substance Use, Abuse, and Addiction Research at NIH

April 27-28, 2009

- Lawrence A. Tabak, D.D.S., Ph.D., Director, National Institute of Dental and Craniofacial Research, and Acting Deputy Director, NIH
- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, NIH
- Kenneth R. Warren, Ph.D., Acting Director, National Institute on Alcohol Abuse and Alcoholism, NIH

September 23, 2009

Prevention Specialists

- Nancy Freudenthal, First Lady of Wyoming
- Sheppard Kellam, M.D., Professor Emeritus, Johns Hopkins Bloomberg School of Public Health

Treatment Providers

- Herbert D. Kleber, M.D., Professor of Psychiatry, Columbia University College of Physicians and Surgeons, and Director, Division on Substance Abuse, New York State Psychiatric Institute
- Marc A. Schuckit, M.D., Professor of Psychiatry, University of California, San Diego; and Director, Alcohol Research Center and the Alcohol & Drug Treatment Program, VA San Diego Healthcare System

Patient Advocates

- Tom Donaldson, President, National Organization on Fetal Alcohol Syndrome
- Sue Rusche, President and CEO, National Families in Action; and Chief Architect, Parent Corps

Public Policy Specialists

- John Carnevale, Ph.D., Carnevale Associates, LLC

Cellular and Molecular Science

- Huda Akil, Ph.D., Professor and Senior Research Scientist, Department of Psychiatry, and Co-Director, Mental Health Research Institute, University of Michigan
- R. Adron Harris, Ph.D., June and J. Virgil Waggoner Chair in Molecular Biology, and Director, Waggoner Center for Alcohol and Addiction Research, University of Texas at Austin

Systems Science

- Michael Charness, M.D., Chief of Staff, VA Boston Healthcare System; Professor of Neurology and Faculty Associate Dean, Harvard Medical School; Assistant Dean, Boston University School of Medicine; and Scientific Director, NIAAA Consortium Initiative on Fetal Alcohol Spectrum Disorders
- Mary Jeanne Kreek, M.D., Professor and Head of Laboratory, Laboratory of the Biology of Addictive Diseases, Rockefeller University; and Senior Physician, Rockefeller University Hospital

Behavior Science

- Mark S. Goldman, Ph.D., Research Professor and Director, Alcohol and Substance Use Research Institute, University of South Florida
- Linda Porrino, Ph.D., Professor and Chair, Department of Physiology and Pharmacology, Director, Neuroimaging Laboratory, and Scientific Director, Center for the Neurobiological Investigation of Drug Abuse, Wake Forest University School of Medicine; and President, College on Problems of Drug Dependence

Treatment/Relapse

- Thomas R. Kosten, M.D., Waggoner Chair and Professor of Psychiatry, Pharmacology, and Neuroscience, Baylor College of Medicine; and Research Director, Substance Use Disorders Quality Enhancement Research Initiative, U.S. Department of Veterans Affairs
- Stephanie O'Malley, Ph.D., Professor and Director, Division of Substance Abuse Research, Department of Psychiatry, Yale University School of Medicine; and Director of Addiction Services, Connecticut Mental Health Center

Consequences

- Scott Friedman, M.D., Chief and Senior Attending Physician, Division of Liver Diseases, Mount Sinai School of Medicine
- David Vlahov, Ph.D., R.N., Director for the Center for Urban Epidemiologic Studies, New York Academy of Medicine; Professor of Clinical Epidemiology, Mailman School of Public Health at Columbia University; and Adjunct Professor of Epidemiology, Johns Hopkins Bloomberg School of Public Health

Policy Research

- Thomas Greenfield, Ph.D., Scientific Director, Alcohol Research Group, Public Health Institute; and Adjunct Clinical Faculty, Clinical Services Research Program, Department of Psychiatry, University of California, San Francisco
- David Rosenbloom, Ph.D., President and CEO, National Center on Addiction and Substance Abuse, Columbia University

October 14, 2009

Judicial System

- Linda Chezem, J.D., Professor, Youth Development and Agricultural Education, College of Agriculture, Purdue University
- Pamela Rodriguez, President, TASC, Inc.

Academia

- Steven E. Hyman, M.D., Provost, Harvard University; Professor of Neurobiology, Harvard Medical School
- John H. Krystal, M.D., Deputy Chairman of Research, Department of Psychiatry, and Director, NIAAA Center for the Translational Neuroscience of Alcoholism, Yale School of Medicine; and Director, Clinical Neuroscience Division, National Center for PTSD, and Director, Alcohol Research Center, U.S. Department of Veterans Affairs

Industry

- Bankole Johnson, D.Sc., M.D., Ph.D., M.Phil., F.R.C.Psych., Chair of Psychiatric Medicine, Department of Psychiatry and Neurobehavioral Sciences, University of Virginia

- Steven M. Paul, M.D., Executive Vice President, Science and Technology, and President, Lilly Research Laboratories, Eli Lilly and Company

December 22, 2009

- Enoch Gordis, M.D., Director, National Institute on Alcohol Abuse and Alcoholism, NIH, 1986 - 2001
- Alan Leshner, Ph.D., Director, National Institute on Drug Abuse, NIH, 1994 - 2001
- Ting-Kai Li, M.D., Director, National Institute on Alcohol Abuse and Alcoholism, NIH, 2002 - 2008

March 10, 2010

- Hal G. Rainey, Ph.D., M.A., Alumni Foundation Distinguished Professor and Ph.D. Director, Department of Public Administration and Policy, University of Georgia

May 18, 2010

Members of the Community

- John Carnevale, Ph.D., President, Carnevale Associates, LLC
- Robert Carothers, Ph.D., J.D., Past President, University of Rhode Island
- Mimi Fleury, Chair, Substance Abuse Manual Committee; and President and Co- Founder, Community of Concern, Inc.
- Nancy Freudenthal, First Lady of Wyoming
- Flo Hilliard, M.S.H., Faculty Associate, Division of Continuing Studies, Professional Development and Applied Studies, University of Wisconsin-Madison
- Sue Rusche, Co-Founder, President, and CEO, National Families in Action; and Chief Architect, Parent Corps

Specialists on Behavior, Treatment, and Prevention

- Richard Catalano, Ph.D., Director, Social Development Research Group, School of Social Work, and Adjunct Professor of Education and Sociology, University of Washington
- Anita Smith Everett, M.D., Section Director and Assistant Professor, Community and General Psychiatry, Johns Hopkins Bayview Medical Center
- Peter Monti, Ph.D., Donald G. Millar Distinguished Professor of Alcohol and Addiction Studies, and Director, Center for Alcohol and Addiction Studies, Brown University
- Marc A. Schuckit, M.D., Distinguished Professor of Psychiatry, University of California, San Diego; and former Director, Alcohol Research Center and Alcohol & Drug Treatment Program, VA San Diego Healthcare System

Early Stage Investigators

- Laura M. Bohn, Ph.D., Associate Professor, Departments of Molecular Therapeutics and Neuroscience, The Scripps Research Institute
- Adam C. Brooks, Ph.D., Research Scientist, Treatment Research Institute
- Sherry McKee, Ph.D., Director, Yale Behavioral Pharmacology Laboratory, and Associate Professor of Psychiatry, Yale University
- Kimberly Nixon, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, University of Kentucky

NIH Grant Holders

- K. Michael Cummings, Ph.D., M.P.H., Chair, Department of Health Behavior, Roswell Park Cancer Institute; and Professor, Department of Social and Preventive Medicine, School of Public Health and Health Professions, University at Buffalo, The State University of New York
- Bankole Johnson, D.Sc., M.D., Ph.D., M.Phil., F.R.C.Psych., Chair of Psychiatric Medicine, Department of Psychiatry and Neurobehavioral Sciences, University of Virginia
- Peter W. Kalivas, Ph.D., Professor and Co-Chair, Department of Neurosciences, Medical University of South Carolina
- Charles P. O'Brien, M.D., Ph.D., Kenneth Appel Professor of Psychiatry, Department of Psychiatry, School of Medicine; and The Mahoney Institute of Neurological Sciences, University of Pennsylvania
- Adolf Pfefferbaum, M.D., Professor Emeritus, Department of Psychiatry and Behavioral Sciences, Stanford University; Senior Administrative Psychiatrist, California Division of Juvenile Justice; and Director, Neuroscience Program, SRI International
- Marc N. Potenza, M.D., Ph.D., Director, Problem Gambling Clinic, and Director, Women and Addictive Disorders Core, Women's Health Research, Yale University; and Associate Professor of Psychiatry and Child Study, Division of Substance Abuse, Yale School of Medicine
- Cary R. Savage, Ph.D., Director, Functional MRI, Hoglund Brain Imaging Center, and Professor, Department of Psychiatry and Behavioral Sciences, University of Kansas Medical Center

Reflections from Current NIDA and NIAAA Directors

- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, NIH
- Kenneth R. Warren, Ph.D., Acting Director, National Institute on Alcohol Abuse and Alcoholism, NIH

4) Please provide examples of how NIH could consider resource allocation to more closely match the public health burdens? Plus, explain the benefits of changing the resource allocation in this manner.

Answer: NIH presently allocates its resources based on multiple factors, including but not limited to: public health burden; scientific opportunity; the quality of research as determined through competitive peer review; maintaining a broad portfolio, including support for the infrastructure of research; and financial commitments from ongoing research. This multifactor approach is by necessity dynamic, and the weight of each factor varies from year to year depending upon current conditions and unexpected alterations to those conditions. For this reason, there is no single formula for resource allocation; instead NIH must determine allocations based on a balance between strategic planning and responding to unexpected scientific opportunities or newly emerging public health threats.

While NIH could consider allocation methods that attempt to match more closely the relative share of resources requested to fit various measures of the perceived burden of illness or other conditions afflicting the U.S. public, for example, Years of Potential Life Lost, such an approach has numerous disadvantages that outweigh any apparent advantages.

Due to the dynamic nature of science, NIH will continue to allocate funding based on scientific opportunities that show great promise for impacting a range of public health burdens. However, basic research which uncovers the fundamental principles of biology, wellness, disease, and public health, is also paramount to understanding the causes of disease onset and progression, designing preventive interventions, developing better diagnostic tests, and discovering new treatments and cures. NIH invests slightly over half its budget on such research. Much of this research applies to numerous diseases and disorders. For example, by gaining understanding of fundamental genetic mechanisms and the technology for examining them, genetic variants associated with disease are being identified at a stunning rate, laying the groundwork for new diagnostic tools and novel drug targets for any number of

heritable disorders, as well as providing valuable insights into common biological pathways and biochemical and molecular mechanisms, insights that inform many areas of biomedicine. Some allocations are investments in scientific areas of inquiry that are likely to have high future-year payoffs for furthering NIH's mission.

As a Federal agency, NIH also has a distinct obligation not only to address but to emphasize research in areas that do not attract private sector interest. There are approximately 5,000 to 7,000 rare diseases alone, afflicting millions of Americans, in which the greatest hope for prevention and cure lies with NIH research. These diseases, should allocation be based on prevalence and incidence statistics alone, would receive very little funding from NIH according to traditional definitions of burden of illness. In addition, by studying rare diseases, much can be learned that would apply to other, more prevalent diseases as well.

For these reasons, NIH allocates funding via grants, contracts and agreements based on a dynamic multi-factorial approach that relies on the input of its many stakeholders, including the scientific community and the public. NIH's distribution of resources reflects the particular advantages of an objective, professional, and consensus-driven peer review process for the award of grants.

5) Please provide a breakout, by IC and in total, of the percentage and dollar amount of the Research Project Grants (RPGs) awarded with Requests for Applications (RPA), Program Announcements (PAs), and Unsolicited (or Investigator Initiated) for FY 2010, FY 2011, FY 2012, and projected for FY 2013.

Answer: The information for competing research project grants is as follows:

NIH Competing Research Project Grant Awards and Percent of Award by IC and Source of Application

IC	Application Submitted in response to:	FY 2010		FY 2011		FY 2012 (awards as of April 20, 2012)		FY 2013*	
		Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Partial Year Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Projected RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards
NIH TOTAL									
FIC[1]	PA	$2,548,797	100.0%	$2,389,671	100.0%	$574,546	100.0%	$2,110,624	60.1%
FIC	RFA	$0	0.0%	$0	0.0%	$0	0.0%	$1,399,376	39.9%
FIC Total		**$2,548,797**	**100.0%**	**$2,389,671**	**100.0%**	**$574,546**	**100.0%**	**$3,510,000**	**100.0%**
NCCAM	PA	$13,016,214	54.1%	$6,186,073	27.3%	$114,000	3.5%	$13,744,758	59.4%
NCCAM	RFA	$7,476,721	31.0%	$7,820,359	34.6%	$1,712,070	52.2%	$3,998,988	17.3%
NCCAM	Unsolicited	$3,587,437	14.9%	$8,612,067	38.1%	$1,452,821	44.3%	$5,400,254	23.3%
NCCAM Total		**$24,080,372**	**100.0%**	**$22,618,499**	**100.0%**	**$3,278,891**	**100.0%**	**$23,144,000**	**100.0%**
NCI	PA	$160,110,055	31.0%	$153,699,383	36.2%	$25,625,415	28.7%	$120,079,784	26.8%
NCI	RFA	$68,539,452	13.3%	$32,130,872	7.6%	$0	0.0%	$44,695,875	10.0%
NCI	Unsolicited	$287,948,728	55.7%	$238,663,331	56.2%	$63,537,453	71.3%	$283,051,341	63.2%
NCI Total		**$516,598,235**	**100.0%**	**$424,493,586**	**100.0%**	**$89,162,868**	**100.0%**	**$447,827,000**	**100.0%**
IC	Application Submitted in response to:	FY 2010		FY 2011		FY 2012 (awards as of April 20, 2012)		FY 2013*	
		Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Partial Year Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Projected RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards
NCRR[2]	PA	$3,446,372	28.9%	$4,804,835	40.0%	N/A	N/A	N/A	N/A
NCRR	RFA	$5,488,257	46.0%	$5,158,559	42.9%	N/A	N/A	N/A	N/A

NCRR	Unsolicited	$2,986,347	25.1%	$2,052,687	17.1%	N/A	N/A	N/A	N/A
NCRR Total		**$11,920,976**	**100.0%**	**$12,016,081**	**100.0%**	**N/A**	**N/A**	**N/A**	**N/A**
NCATS[2]	PA	N/A	N/A	N/A	N/A	$0	0.0%	$6,910,530	35.1%
NCATS	RFA	N/A	N/A	N/A	N/A	$0	0.0%	$7,178,176	36.4%
NCATS	Unsolicited	N/A	N/A	N/A	N/A	$0	0.0%	$5,608,294	28.5%
NCATS Total		**N/A**	**N/A**	**N/A**	**N/A**	**$0**	**0.0%**	**$19,697,000**	**100.0%**
NEI	PA	$2,331,295	2.4%	$4,071,436	3.6%	$221,766	0.4%	$6,564,665	5.8%
NEI	RFA	$2,262,500	2.3%	$2,629,952	2.3%	$743,334	1.3%	$901,340	0.8%
NEI	Unsolicited	$91,813,573	95.2%	$106,829,439	94.1%	$54,766,211	98.3%	$105,417,995	93.4%
NEI Total		**$96,407,368**	**100.0%**	**$113,530,827**	**100.0%**	**$55,731,311**	**100.0%**	**$112,884,000**	**100.0%**
NHGRI	PA	$6,025,790	20.2%	$8,763,789	22.3%	$1,335,568	6.8%	$5,289,324	13.1%
NHGRI	RFA	$8,744,013	29.4%	$14,371,352	36.5%	$15,751,271	79.8%	$19,951,575	49.5%
NHGRI	Unsolicited	$14,987,198	50.4%	$16,221,837	41.2%	$2,643,128	13.4%	$15,052,101	37.4%
NHGRI Total		**$29,757,000**	**100.0%**	**$39,356,978**	**100.0%**	**$19,729,967**	**100.0%**	**$40,293,000**	**100.0%**
NHLBI	PA	$35,862,658	7.7%	$83,397,519	18.7%	$29,159,174	17.5%	$47,512,564	10.8%
NHLBI	RFA	$72,495,840	15.5%	$52,984,867	11.9%	$17,856,451	10.7%	$55,210,375	12.5%
NHLBI	Unsolicited	$359,696,502	76.8%	$309,592,768	69.4%	$119,593,626	71.8%	$338,277,062	76.7%
NHLBI Total		**$468,055,000**	**100.0%**	**$445,975,154**	**100.0%**	**$166,609,251**	**100.0%**	**$441,000,000**	**100.0%**
NIA	PA	$16,658,040	11.7%	$30,275,052	19.2%	$8,449,900	22.0%	$22,566,173	13.5%
NIA	RFA	$11,969,379	8.4%	$10,898,195	6.9%	$13,381,000	34.8%	$16,204,148	9.7%
NIA	Unsolicited	$113,903,180	79.9%	$116,908,660	74.0%	$16,650,825	43.3%	$128,024,679	76.8%
NIA Total		**$142,530,599**	**100.0%**	**$158,081,907**	**100.0%**	**$38,481,725**	**100.0%**	**$166,795,000**	**100.0%**

IC	Application Submitted in response to:	FY 2010		FY 2011		FY 2012 (awards as of April 20, 2012)		FY 2013*	
		Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Partial Year Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Projected RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards
NIAAA	PA	$24,643,118	36.6%	$14,183,203	26.7%	$6,554,689	45.2%	$14,888,062	27.1%
NIAAA	RFA	$13,100,185	19.4%	$17,368,410	32.7%	$4,251,710	29.3%	$13,024,989	23.7%
NIAAA	Unsolicited	$29,640,894	44.0%	$21,599,889	40.6%	$3,687,157	25.4%	$26,950,949	49.1%
NIAAA Total		**$67,384,197**	**100.0%**	**$53,151,502**	**100.0%**	**$14,493,556**	**100.0%**	**$54,864,000**	**100.0%**
NIAID	PA	$30,387,438	6.0%	$49,172,769	10.3%	$7,936,892	4.3%	$55,960,088	8.6%
NIAID	RFA	$120,927,107	23.8%	$129,931,115	27.3%	$23,405,893	12.8%	$197,753,492	30.3%
NIAID	Unsolicited	$356,066,454	70.2%	$296,891,649	62.4%	$151,513,009	82.9%	$399,578,420	61.2%
NIAID Total		**$507,381,000**	**100.0%**	**$475,995,533**	**100.0%**	**$182,855,794**	**100.0%**	**$653,292,000**	**100.0%**
NIAMS	PA	$10,427,753	11.1%	$10,841,864	14.1%	$2,754,678	16.0%	$9,981,624	12.5%
NIAMS	RFA	$4,561,715	4.9%	$2,724,720	3.5%	$0	0.0%	$4,617,538	5.8%
NIAMS	Unsolicited	$78,897,089	84.0%	$63,395,515	82.4%	$14,472,069	84.0%	$64,998,838	81.7%
NIAMS Total		**$93,886,557**	**100.0%**	**$76,962,099**	**100.0%**	**$17,226,747**	**100.0%**	**$79,598,000**	**100.0%**
NIBIB	PA	$22,542,330	32.2%	$24,659,565	40.5%	$7,323,363	41.4%	$27,371,445	39.5%
NIBIB	RFA	$10,283,040	14.7%	$2,199,489	3.6%	$0	0.0%	$6,021,700	8.7%
NIBIB	Unsolicited	$37,212,419	53.1%	$33,971,946	55.8%	$10,363,335	58.6%	$35,911,855	51.8%
NIBIB Total		**$70,037,789**	**100.0%**	**$60,831,000**	**100.0%**	**$17,686,698**	**100.0%**	**$69,305,000**	**100.0%**
NICHD	PA	$26,735,981	16.9%	$29,139,020	18.0%	$18,773,469	27.3%	$24,366,964	16.4%
NICHD	RFA	$20,131,762	12.7%	$41,969,486	26.0%	$4,548,295	6.6%	$24,978,438	16.8%
NICHD	Unsolicited	$111,182,847	70.3%	$90,515,494	56.0%	$45,391,778	66.1%	$98,899,598	66.7%
NICHD Total		**$158,050,590**	**100.0%**	**$161,624,000**	**100.0%**	**$68,713,542**	**100.0%**	**$148,245,000**	**100.0%**
NIDA	PA	$56,167,222	37.1%	$46,507,173	38.8%	$26,515,450	48.6%	$55,903,699	34.9%
NIDA	RFA	$46,999,209	31.1%	$19,741,898	16.5%	$7,994,509	14.6%	$35,190,019	22.0%
NIDA	Unsolicited	$48,128,000	31.8%	$53,534,869	44.7%	$20,103,808	36.8%	$68,958,282	43.1%
NIDA Total		**$151,294,431**	**100.0%**	**$119,783,940**	**100.0%**	**$54,613,767**	**100.0%**	**$160,052,000**	**100.0%**

IC	Application Submitted in response to:	FY 2010		FY 2011		FY 2012 (awards as of April 20, 2012)		FY 2013*	
		Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Partial Year Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Projected RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards
NIDCD	PA	$16,107,623	24.3%	$11,688,704	17.4%	$4,915,387	16.9%	$12,824,079	20.4%
NIDCD	RFA	$650,695	1.0%	$3,700,980	5.5%	$0	0.0%	$1,217,592	1.9%
NIDCD	Unsolicited	$49,548,254	74.7%	$51,757,660	77.1%	$24,195,936	83.1%	$48,677,328	77.6%
NIDCD Total		**$66,306,572**	**100.0%**	**$67,147,344**	**100.0%**	**$29,111,323**	**100.0%**	**$62,719,000**	**100.0%**
NIDCR	PA	$11,559,356	17.4%	$13,939,719	21.7%	$3,459,687	12.5%	$12,376,116	19.2%
NIDCR	RFA	$12,422,501	18.7%	$11,504,905	17.9%	$9,976,266	36.2%	$12,106,768	18.8%
NIDCR	Unsolicited	$42,509,408	63.9%	$38,851,421	60.4%	$14,150,355	51.3%	$39,817,116	61.9%
NIDCR Total		**$66,491,265**	**100.0%**	**$64,296,045**	**100.0%**	**$27,586,308**	**100.0%**	**$64,300,000**	**100.0%**
NIDDK	PA	$45,734,857	13.7%	$59,574,092	15.9%	$10,672,323	20.1%	$53,379,024	14.5%
NIDDK	RFA	$36,093,776	10.8%	$123,089,711	32.9%	$1,929,110	3.6%	$89,108,605	24.2%
NIDDK	Unsolicited	$251,761,339	75.5%	$191,096,196	51.1%	$40,577,446	76.3%	$225,516,372	61.3%
NIDDK Total		**$333,589,972**	**100.0%**	**$373,760,000**	**100.0%**	**$53,178,879**	**100.0%**	**$368,004,000**	**100.0%**
NIEHS	PA	$5,180,342	8.1%	$6,728,217	12.2%	$1,870,984	9.7%	$4,393,473	7.8%
NIEHS	RFA	$14,926,563	23.3%	$12,320,851	22.3%	$3,354,236	17.5%	$20,306,402	36.0%
NIEHS	Unsolicited	$43,838,095	68.6%	$36,177,274	65.5%	$13,985,758	72.8%	$31,741,125	56.2%
NIEHS Total		**$63,945,000**	**100.0%**	**$55,226,342**	**100.0%**	**$19,210,978**	**100.0%**	**$56,441,000**	**100.0%**
NIGMS	PA	$26,627,855	7.9%	$31,732,644	9.1%	$10,154,320	7.9%	$32,787,418	9.5%
NIGMS	RFA	$43,446,777	12.9%	$23,950,595	6.9%	$2,520,434	2.0%	$27,812,355	8.1%
NIGMS	Unsolicited	$266,154,182	79.2%	$292,070,761	84.0%	$115,699,125	90.1%	$283,445,226	82.4%
NIGMS Total		**$336,228,814**	**100.0%**	**$347,754,000**	**100.0%**	**$128,373,879**	**100.0%**	**$344,045,000**	**100.0%**
NIMH	PA	$66,365,582	28.6%	$39,807,296	21.7%	$13,248,368	19.1%	$72,237,528	31.4%
NIMH	RFA	$25,995,840	11.2%	$31,343,803	17.1%	$2,731,367	3.9%	$31,479,027	13.7%
NIMH	Unsolicited	$139,971,449	60.2%	$111,884,037	61.1%	$53,492,530	77.0%	$126,210,444	54.9%
NIMH Total		**$232,332,871**	**100.0%**	**$183,035,136**	**100.0%**	**$69,472,265**	**100.0%**	**$229,927,000**	**100.0%**

IC	Application Submitted in response to:	FY 2010		FY 2011		FY 2012 (awards as of April 20, 2012)		FY 2013#	
		Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Actual Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Partial Year Awarded RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards	Projected RPGs (Competing awards only)	Percent of IC's Total Competing RPG Awards
NIMHD[1]	PA	$0	0.0%	$291,424	6.3%	$0	0.0%	$97,481	1.7%
NIMHD	RFA	$8,355,341	100.0%	$4,121,108	89.2%	$4,190,209	100.0%	$5,617,519	98.3%
NIMHD	Unsolicited	$0	0.0%	$205,344	$0	0.0%	$0	0.0%	0.0%
NIMHD Total		**$8,355,341**	**100.0%**	**$4,617,876**	**95.6%**	**$4,190,209**	**100.0%**	**$5,715,000**	**100.0%**
NINDS	PA	$44,278,394	15.6%	$56,092,677	19.1%	$7,674,255	9.7%	$54,986,528	18.5%
NINDS	RFA	$13,302,357	4.7%	$20,843,928	7.1%	$1,255,760	1.6%	$14,344,035	4.8%
NINDS	Unsolicited	$225,690,892	79.7%	$217,031,396	73.8%	$70,101,291	88.7%	$227,325,437	76.6%
NINDS Total		**$283,271,643**	**100.0%**	**$293,968,001**	**100.0%**	**$79,031,306**	**100.0%**	**$296,656,000**	**100.0%**
NINR	PA	$4,723,401	20.1%	$3,653,172	15.7%	$2,445,720	38.8%	$6,910,826	22.3%
NINR	RFA	$5,541,871	23.6%	$7,272,250	31.3%	$144,830	2.3%	$5,928,841	19.1%
NINR	Unsolicited	$13,215,246	56.3%	$12,324,035	53.0%	$3,714,074	58.9%	$18,194,333	58.6%
NINR Total		**$23,480,518**	**100.0%**	**$23,249,457**	**100.0%**	**$6,304,624**	**100.0%**	**$31,034,000**	**100.0%**
NLM	PA	$3,903,916	45.4%	$2,575,686	41.9%	$349,313	39.9%	$2,053,180	30.6%
NLM	RFA	$0	0.0%	$0	0.0%	$325,163	37.1%	$149,451	2.2%
NLM	Unsolicited	$4,696,718	54.6%	$3,565,707	58.1%	$201,915	23.0%	$4,511,369	67.2%
NLM Total		**$8,600,634**	**100.0%**	**$6,141,393**	**100.0%**	**$876,391**	**100.0%**	**$6,714,000**	**100.0%**
OD	PA	$11,710,150	7.7%	$16,674,778	12.2%	$410,500	51.5%	$0	0.0%
OD	RFA	$137,436,807	90.2%	$115,705,984	84.8%	$0	0.0%	170,405,000	100.0%
OD	Unsolicited	$3,153,501	2.1%	$4,089,380	3.0%	$386,250	48.5%	$0	0.0%
OD Total		**$152,300,459**	**100.0%**	**$136,470,142**	**100.0%**	**$796,750**	**100.0%**	**170,405,000**	**100.0%**

	Application Submitted in response to:	FY 2010		FY 2011		FY 2012		FY 2013*	
		Actual Awarded RPGs (Competing awards only)	Percent of NIH's Total Competing RPG Awards	Actual Awarded RPGs (Competing awards only)	Percent of NIH's Total Competing RPG Awards	Partial Year Awarded RPGs (Competing awards only)	Percent of NIH's Total Competing RPG Awards	Projected RPGs (Competing awards only)	Percent of NIH's Total Competing RPG Awards
NIH total	PA	$647,094,539	16.5%	$710,688,774	19.1%	$190,539,767	16.6%	$665,295,958	16.4%
NIH total	RFA	$691,151,708	17.7%	$693,452,056	18.6%	$116,071,908	10.1%	$809,601,625	20.0%
NIH total	Unsolicited	$2,576,589,752	65.8%	$2,317,327,170	62.3%	$840,679,900	73.3%	$2,581,568,417	63.6%
NIH total		**$3,914,836,000**	**100.0%**	**$3,721,468,000**	**100.0%**	**$1,147,291,575**	**100.0%**	**$4,056,466,000**	**100.0%**

Notes: As requested in the Question for the Record, this report deviates from NIH's standard reporting process by reporting Program Announcements (PA), including those involving a dedicated locus of review (PAR) and those involving a dedicated financial commitment (PAS) as a separate line item from the awards submitted in response to the Parent Funding Opportunity Announcement (Unsolicited).

Excludes awards made with American Recovery and Reinvestment Act (ARRA) funds.

Research Project Grants are defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

[1] There were no unsolicited RPGs awarded by Fogarty International Center (FIC) or the National Institute of Minority and Health Disparities (NIMHD) during the time period of this report.

[2] As part of the Fiscal Year 2012 Omnibus Appropriations bill, the National Center for Research Resources (NCRR) is dissolved and the National Center for Advancing Translational Sciences (NCATS) is established. NCATS has made no competing awards in FY 2012 as of April 20.

* Projections for FY 2013 were calculated using FY 2007 – FY 2011 funding history. However, FY 2013 projections for NCATS are based on the previous funding history of NCRR given the absence of full year grant operation experience specific to NCATS.

6) The House FY 2007 Appropriation Report included a NIH section on "Priority Setting" that directed each NIH IC to undertake a strategic planning process. Please provide an update by IC to this report that identifies the last time each strategic plan was updated. Plus, identify the FY 2007 baseline measures for each IC and the FY 2011 actual, FY 2012 and FY 2013 target measures related to the required element in the strategic plan to increase the IC's emphasis on requests for applications (RFAs) that identified specific research themes to achieve strategic goals. If the goals were not achieved, explain how the plan was or will be addressed to accomplish the goals. Please explain, by IC, the tactical steps each has taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases.

Answer: The following pages include the requested information organized by NIH Institute and Center.

Fogarty International Center (FIC)

Current Strategic Plan
The FIC strategic plan was last updated in May 2008.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	1	3	2	2
Contributed to by IC*	0	0	1*	Not Available*

*Please note, FIC does not develop targets for contributing to RFAs. FIC determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 number shown is actual to date.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
The Fogarty International Center's Strategic Plan is organized around five strategic goals and will guide the Center's activities through the end of 2012. First, it provides an increased focus on chronic non-communicable diseases while continuing to address the unfinished infectious diseases agenda. Second, the plan highlights the importance of implementation science to address the "know-do" gap and the need to train scientists in this field. Third, it builds on Fogarty's unique strength in supporting research training opportunities for U.S. and foreign scientists. Fourth, it sets out a vision to foster a sustainable research environment in low- and middle-income countries. Fifth, it calls for building strategic partnerships to further global health research and research capacity-building. The majority of FIC's extramural activities aimed at accomplishing the goals of its strategic plan are undertaken through Program Announcements in addition to RFAs. To implement its Strategic Plan, Fogarty has taken the following steps, among others:

- In response to the growing global burden of chronic, non-communicable diseases, Fogarty created the Millennium Promise Awards, with initial grants totaling $7.3 million over five years, to support local institutions to develop training and research programs to identify novel approaches to reduce the burden of chronic disease. Currently, the Chronic, Non-Communicable Diseases and Disorders Across the Lifespan: Fogarty

International Research Training Award (NCD-LIFESPAN) D43 program for collaborative research training between institutions in the U.S. and low-and middle-income countries (LMIC) aims to strengthen the research capacity of the LMIC institutions, and to train in-country experts to conduct research on chronic, non-communicable diseases and disorders across the lifespan, with the ultimate goal of implementing evidence-based interventions relevant to their countries.

- Training in implementation science is supported under several diverse Fogarty programs, including the International Tobacco and Health Research and Capacity Building Program, the AIDS International Research and Training Program, Brain Disorders in the Developing World: Research Across the Lifespan, and the NCD-Lifespan Program. Fogarty is also a partner with the National Institute of Child Health and Development on the NIH/PEPFAR Collaboration for advancing Implementation Science in Prevention of Mother-to-Child HIV Transmission.
- To continue developing the pipeline of U.S. and foreign research talent, FIC established the Fogarty International Clinical Research Scholars Program, which provides opportunities for new U.S. investigators seeking hands-on experience working in developing countries and pairs them to early career foreign health scientists who work alongside the U.S. trainee during the clinical research year. The most recent version of the Fogarty Global Health Program for Fellows and Scholars provides five consortia of academic institutions with funding to support the training activities of a total of 20 partner institutions. Each consortium will develop and support global health research training programs that provide focused mentoring for participants and diverse clinical research experiences at approximately 80 established research sites in low-resource settings. Program trainees will study the traditional global health problems such as HIV/AIDS, tuberculosis, malaria and maternal and child health, and will address the chronic non-communicable diseases that cause a majority of deaths in developing countries, such as cancer, cardiovascular disease and diabetes. Simultaneously, research training of overseas scientists remains a high priority for Fogarty. Fogarty continues to invest in training programs which have helped to train over 6,000 individuals around the world since its establishment by Congress in 1968.
- Over the past few decades, Fogarty investments have greatly enhanced the number of trained foreign investigators working at research institutions abroad. To support the strengthening of sustainable research environments at these institutions so that scientists have the necessary support to conduct their research, Fogarty invests in cross-cutting areas that include informatics training for global health research, training and curriculum development in research ethics, and research management. An additional priority has been support for the establishment of linkages or hubs for sharing resources and knowledge across sites in particular areas of expertise. An example of such an investment is the RFA for Planning Grants for Hubs of Interdisciplinary Research and Training in Global Environmental and Occupational Health.
- In addition to numerous partnerships with other NIH Institutes and Centers across Fogarty's portfolio, Fogarty is administering a major new program called the Medical Education Partnership Initiative (MEPI) - a joint effort of the Office of the Global AIDS Coordinator, the Health Resources and Services Administration, the Department of Defense, USAID, CDC, and NIH. MEPI supports institutions in Sub-Saharan African countries and their U.S. partners to develop new models of medical education and to strengthen the ability of medical students and faculty to conduct research that responds to the health needs of their countries.

National Center for Advancing Translational Sciences (NCATS)

The NCATS was created on December 23, 2011 with the passage of the Consolidated Appropriations Act, 2012 (P.L. 112-74). A strategic plan will be developed once permanent leadership is in place.

National Center for Complementary and Alternative Medicine (NCCAM)

Current Strategic Plan

The NCCAM strategic plan was last updated in February 2011.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	6	3	1	4
Contributed to by IC*	9	13	8*	5*

*Targets based on information available to date.

Narrative Response:

In addition to RFAs, NCCAM uses a variety of other methods to foster research in high priority areas. These include program announcements (PAs) and request for proposals (RFPs). NCCAM also lists research areas of special interest on the Center's Web site to encourage investigators to submit proposals in these areas.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

NCCAM's third strategic plan, *Exploring the Science of Complementary and Alternative Medicine* (released February 2011) includes three overarching goals to: (1) advance the science and practice of symptom management; (2) develop effective, practical, personalized strategies for promoting health and well-being; and (3) enable better evidence-based decision making regarding use of complementary approaches and their integration into improved strategies for health care and health promotion.

NCCAM's strategic plan implementation and funding decisions are guided by a priority setting framework. Specifically, NCCAM uses the framework (as outlined below) to assist in (1) identifying and shaping targeted research initiatives (including RFAs); (2) identifying the most critical knowledge gaps in advancing research on particular complementary interventions, practices, or disciplines; and (3) striking the proper balance between targeted research initiatives and investigator-initiated projects. Additionally, NCCAM uses this framework to identify high program priority investigator-initiated grants.

NCCAM-Initiated Research:

Using the strategic plan and the priority setting framework as blueprints, NCCAM is investing in priority areas through the issue of PAs, RFAs, and RFPs. Concepts for initiatives are developed by NCCAM staff (in consultation with other NIH staff and external stakeholders) after a thorough analysis of the NCCAM and NIH complementary intervention research portfolios and identification of areas that require targeted initiatives (i.e., PAs, RFAs, and RFPs).

Investigator-Initiated Research:
In addition to NCCAM-initiated research, NCCAM encourages investigators to submit applications in priority research areas aligned with the goals of the strategic plan. This is accomplished by posting information about areas of special interest on the NCCAM Web site and disseminating information through webinars, conferences, and staff presentations at scientific meetings.

Framework for Priority Setting:
To help ensure NCCAM's investments are directed toward research that offers the most potential for adding significant value to public health, NCCAM considers the following four factors when setting its research priorities:

- *Scientific Promise:* Does a reasonable body of evidence support the potential of the proposed research to lead to improved (1) options or strategies to treat troubling or prevalent health conditions or symptoms or (2) approaches to promote better health and well-being?
- *Amenability to Rigorous Scientific Inquiry:* Are the key research goals achievable, and are the key research questions amenable to rigorous scientific investigation, given needed and available methods for measurement, translational tools, and technologies?
- *Potential to Change Health Practices:* Is it reasonably likely that the results of the research or program could lead to changes in the health practices of consumers or health care providers or in the decisions of health policymakers?
- *Relationship to Use and Practice:* Does the proposed project address an important public health concern or scientific information need regarding efficacy, safety, or public use of complementary health practices?

National Cancer Institute (NCI)

Current Strategic Plan
The NCI strategic plan was last updated in April 2011.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	23	22	16	14
Contributed to by IC*	9	8	Not Available*	Not Available*

*NCI does not develop targets for contributing to RFAs. NCI determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Narrative Response:
NCI's scientific goals are addressed by funding a diverse portfolio of unsolicited and solicited extramural projects and also intramural projects. Funding decisions in all of those areas are the result of multiple forms of peer review. Peer reviewers have knowledge of NCI research priorities. NCI conducts ongoing analyses to monitor the research portfolio. When areas of importance are identified as underfunded, the Institute solicits initiatives through Program Announcements, as well as RFAs.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
Funding decisions at the NCI are made according to scientific and strategic priorities. Examples of tactical steps that support NCI's implementation of strategic priorities in cancer research include:

I. Engage and Stimulate the Research Community to Inform Priorities
The cancer research community informs NCI's scientific priorities in many ways, including by defining potentially game-changing scientific questions that will influence the directions taken by NCI-sponsored research. Through the Provocative Questions project, NCI assembled a list of important but non-obvious questions that will stimulate the NCI's research communities to use laboratory, clinical, and population sciences in especially effective and imaginative ways. The questions build on specific advances in our understanding of cancer and cancer control; address broad issues in the biology of cancer that have proven difficult to resolve; take into consideration the likelihood of progress in the foreseeable future; and address ways to overcome obstacles to achieving long-term goals. The collaborative process of formulating the provocative questions engages the NCI's scientific community in serious debate and energizes the NCI's many constituencies (advocacy groups, health professionals, members of Congress, and others) about the prospects for improving the welfare of cancer patients through research.

Provocative Questions posed during nationwide workshops and from website submissions have been selected for inclusion in a Funding Opportunity Announcement (FOA) "Research Answers to NCI's Provocative Questions".

The Request for Applications can currently be viewed at:
http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-11-011.html
http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-11-012.html
The list of questions and supporting information can be found at:
http://provocativequestions.nci.nih.gov/rfa

II. Carefully Review Applications According to Scientific Priorities
Funding decisions at NCI are not simply "payline" driven, but, rather, the leadership reviews the applications carefully to ensure that those funded address scientific priorities. NCI has been paying special attention to applications that might in the past have been unfunded because they fell below what used to be considered a "payline," a percentile score derived from the results of peer review. Beginning in FY 2011, NCI scientific program leaders have been performing additional evaluations of grant applications to ensure a balanced grant portfolio and to recognize the value of research proposals that are highly original or address important scientific priorities, even though they might not have received percentile scores that fall within a pre-determined payline. With the new process, applications that score exceptionally well, falling within the top 7th percentile, almost always receive funding. Applications that score well, but outside of the 7th percentile, are placed in a "zone of uncertainty" and are further evaluated by the NCI's scientific program staff and leadership before a decision is made about recommendation for funding.

III. Ensure the Divisions, Offices, and Centers Align with NCI Priorities
The NCI's Office of Science Planning and Assessment (OSPA) promotes strategic thinking and facilitates on-going planning throughout the Institute to ensure Divisions, Offices, and Centers

align with areas of importance identified by the scientific program leads. The goals of strategic planning are to foster evidence-based decision-making about research funding, improve collaboration and productivity, and optimize the use of available resources. OSPA provides support to many of NCI's Divisions, Offices and Centers through a dynamic strategic planning process to identify stakeholders, inform research priorities, formulate action plans, and evaluate progress.

National Eye Institute (NEI)

Current Strategic Plan
The NEI strategic plan was last updated in 2004; however, a new 3-stage strategic planning effort is ongoing and NEI expects the new plan to be finalized in May 2012. Focused planning workshops to identify emerging gaps and opportunities were completed in 2011.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	0	1	2	2
Contributed to by IC*	0	1	Not Available*	Not Available*

*NEI does not develop targets for contributing to RFAs. NEI determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
Since its inception over 40 years ago, the National Eye Institute (NEI) has engaged in strategic planning activities, which have culminated in a series of national plans and workshop reports that identify needs and opportunities in vision research. The NEI strives to be inclusive by requesting input from the community of vision researchers as well as professional and patient advocacy organizations. NEI planning activities are conducted under the auspices of the National Advisory Eye Council (NAEC), a committee of clinicians, researchers, patients and stakeholders that advises the Institute on funding decisions, initiatives, and strategic planning. The national plan is not intended to be a detailed blueprint for research but is a snapshot that represents the state-of-the-science at the time of publication.

The NEI recognizes that new ideas and concepts are constantly emerging, and that the main engine for scientific discovery is investigator-initiated research. The most important priority is to support the highest quality research that will help achieve the mission of the NEI. As such, the NEI has long relied on investigator-initiated research as the primary means of implementing our priorities. For basic or fundamental research, the emphasis on investigator-initiated research has been achieved primarily through use of the research project grant mechanisms. For applied clinical research, the emphasis on investigator-initiated research has been achieved through cooperative agreements. This has allowed the vision research community to maintain scientific creativity in responding to program priorities identified in the national plans and has resulted in the submission of remarkably creative grant applications that are consistently of high scientific quality.

The NEI leadership and the NAEC have long held the view that the planning process does not necessarily determine the course of scientific discovery, but rather hastens the rate at which it occurs. Even though program planning panels representing the vision research community have identified the priority areas that they consider the most important areas of research, the advent of new technologies or scientific insights always presents the possibility of additional scientific opportunity not foreseen during the plan's development. By encouraging scientific input from broad areas of science and attending scientific meetings to distribute the plans and talk with potential grantees within and outside vision research, the NEI not only has attracted grantees from other scientific disciplines who bring their special expertise to vision research, it has also created the opportunities for participation in a variety of trans-NIH research activities. In other words, an important part of implementation depends on the personal contact of the NEI scientific staff with grantees and potential grantees to encourage and facilitate submission of applications in high priority program areas.

A relatively small number of applications that have been judged to have significant scientific merit in addressing a designated priority or supporting a program goal or objective, and yet are not within the funding range, are brought up by NEI program staff or a member of the National Advisory Eye Council for special council consideration. The Council may designate these applications as having high program relevance and recommend them to the NEI Director for funding. Because vision researchers have been so responsive to the needs and opportunities identified in the strategic plans, NEI has purposefully chosen to limit the issuances of program announcements (PAs) or requests for applications (RFAs). Yet, over the past several years, a small number of RFAs and programs have been launched directly in response to needs and opportunities identified by the NEI's ongoing planning activities. This is expected to expand because as a follow-up to the new planning document, "Vision Research: Needs, Gaps, and Opportunities," the NEI is working with our advisory council to engage a wider community in helping to define the most compelling priorities in vision research today.

National Human Genome Research Institute (NHGRI)

Current Strategic Plan
The NHGRI strategic plan was last updated in February 2011.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	16	7	6	5
Contributed to by IC*	3	3	Not Available*	Not Available*

*NHGRI does not develop targets for contributing to RFAs. NHGRI determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Narrative Response:
The strategic plan identifies five domains of research necessary for the vision of genomic medicine to be realized. The domains emphasize the importance of research on the structure and function of genomes, as well as the need to explore how to apply that knowledge effectively to advance health. The plan provides the framework for the consideration of all existing and new requests for applications (RFAs). The change in the number of RFAs reflects the funding

that NHGRI has chosen to allocate to new RFAs during each year, taking into account the scientific opportunities and overall available funding. The strategic plan will continue to guide the Institute's research portfolio in future years.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
Even before the publication of NHGRI's current strategic plan in February of 2011, the Institute began working internally to examine the extramural portfolio and identify new research areas to support. Since February 2011, NHGRI has held numerous workshops of external scientists to explore specific research areas identified as priorities in the strategic plan. On a regular basis, NHGRI also consults with the National Advisory Council on Human Genome Research on new initiatives, and the extent to which these are in alignment with NHGRI's mission and the strategic plan.

National Heart, Lung, and Blood Institute (NHLBI)

Current Strategic Plan
The NHLBI strategic plan was last updated in September 2007.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	22	25	27	27
Contributed to by IC	9	8	8	8

Narrative Response:
The slightly higher number of "RFAs as contributor" in FY 2007 was due to a project with the NIH Roadmap.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
The NHLBI Strategic Plan, published in 2007, was the result of a three-stage community-based effort to develop a scientific working plan for the next 10 years. The first step of the planning process comprised 23 thematic meetings that incorporated input from approximately 500 investigators. The participants were asked to identify scientific needs and opportunities of pivotal importance and to recommend operational policies to facilitate conduct of high-priority scientific research. The second step brought together members of the National Heart, Lung, and Blood Advisory Council (NHLBAC), chairpersons of the thematic meetings, and other leaders from the research community. Their task was to review the thematic reports, synthesize and prioritize objectives and strategies, determine methods for measuring progress toward achieving objectives, and recommend approaches for fostering development of the research workforce. The final step entailed development of a draft document and its finalization based on comments solicited from patient advocacy groups, professional societies, and other members of the scientific and lay communities.

The Plan is structured around three goals that reflect the successive movement of scientific discovery—from "form to function," "function to causes," and "causes to cures"—and inform

and complement one another. This crosscutting, versus disease-specific, approach highlights areas where the NHLBI is well positioned to make major contributions through investigator-initiated research and through programs that enable and complement investigator-initiated activities. The Plan presents broad strategies to be used by the NHLBI to facilitate the conduct of research; enhance interdisciplinary work; speed early-stage translation of basic discoveries; ensure cross-fertilization of basic, clinical, and epidemiologic discoveries; and maximize the resultant public health benefits.

Investigator-initiated research has long constituted the largest share of the NHLBI research portfolio, and much of the Plan is being realized through continued support of such research. Institute-initiated investments guided by the Plan are directed largely toward programs that either enable or complement investigator-initiated activities. Many such initiatives emanate as RFAs for grants, including cooperative agreements. Each RFA represents the outcome of extensive discussions and thorough reviews by representatives of the scientific community, advisory committees, the NHLBI Board of Extramural Experts (BEE), and the NHLBAC. The advisory committees and the BEE, together with professional societies and NHLBI staff, continually review the progress of NHLBI research relative to the Strategic Plan, assess newly acquired knowledge, and identify research topics that offer the best opportunities or constitute the greatest needs. RFA concepts developed as a result of this process are presented to the BEE and, subsequently, to the NHLBAC for review and comment. Concepts that receive the concurrence of the NHLBAC are considered further by the Institute in the context of budget, program priorities, and other considerations that weigh on the ultimate approval of an RFA for release.

National Institute on Aging (NIA)

Current Strategic Plan
The NIA strategic plan was last updated in November 2007.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	8	10	13	15
Contributed to by IC*	8	15	12	Not Available*

*NIA does not develop targets for contributing to RFAs. NIA determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 number shown is actual to date.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
Decisions about what to fund are guided by the mission and goals of the Institute which cover the full continuum of research from basic discovery to translational research and translation into practice.

- NIA tracks the Institute's portfolio of research by cross-walking funded research projects to strategic goals on an ongoing basis.

- NIA uses this information along with input from the research and provider communities – their proposed research, workshops, conferences, etc. – to identify areas of opportunity and need in each of NIA's goal areas.
- NIA funds research through investigator-initiated applications, coupled with studies proposed in response to Funding Opportunity Announcements (FOAs) such as Requests for Applications (RFAs) and Program Announcements (PAs).

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Current Strategic Plan
The NIAAA strategic plan was last updated in August 2009.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	22	7	8	4
Contributed to by IC*	8	15	16*	Not Available*

*NIAAA does not develop targets for contributing to RFAs. NIAAA determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 number shown is actual to date.

Narrative Response:
With limited funding NIAAA must balance funds provided to applicants in response to RFAs and investigator initiated awards. NIAAA utilizes a number of methods to encourage applications that address key research areas identified in the Institute's strategic plan. In addition to issuing RFAs, NIAAA also issues Program Announcements to indicate interest in a specific research area. NIAAA also collaborates with other ICs in their initiatives by funding projects proximal to NIAAA's mission. Extramural Advisory Board meetings are used to assess the state of the science in a specific area, identify gaps in the research portfolio, plan directions, and lay the groundwork for future initiatives that support the strategic plan. In addition, workshops and panels address under-developed areas of research or services. These activities may also stimulate research applications even in the absence of (or prior to) RFAs being issued.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

- Developed new initiatives in the form of RFAs, PAs, PARs, PASs and RFPs to stimulate research in specific areas of interest to inform prevention and treatment for alcohol use disorders and related conditions.
- Supported meritorious investigator initiated grant applications that focus on research areas that fall under various strategic plan goals.
- Collaborated with other NIH ICs to support multidisciplinary research initiatives in areas including HIV/AIDS, neuroscience, and maternal and child health.
- Leveraged interagency collaborations, including federal coordinating committees, to optimize federal resources and synergize efforts to address alcohol-related public health concerns.

- Conducted workshops and other scientific meetings, such as Extramural Advisory Board meetings, to assess the state of the science, plan specific directions, and encourage collaborative research in support of strategic plan goals.
- Developed and disseminated outreach products for the general public, clinical practitioners, and the research community. Examples include *Rethinking Drinking*, the updated Clinician's Guide and complementary training, the youth screening guide and NIAAA Spectrum.

National Institute of Allergy and Infectious Diseases (NIAID)

Current Strategic Plan
The NIAID strategic plan was last updated in December 2008.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	17	23	20	23
Contributed to by IC*	5	9	Not Available*	Not Available*

*NIAID does not develop targets for contributing to RFAs. NIAID determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

- Research Initiatives Committee established to provide additional expert review of initiatives' relevance, importance, and likelihood of success.
- Increased emphasis on alignment of initiative objectives with NIAID's scientific priorities.
- Improved methods for measuring, monitoring, and reporting performance and results of research initiatives.
- Ongoing monitoring and mapping of investigator-initiated research to understand gaps and research topics in need of stimulation.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Current Strategic Plan
The NIAMS strategic plan was last updated in February 2010.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	4	8	5	4
Contributed to by IC*	5	19	7*	1*

*NIAMS does not develop targets for contributing to RFAs. NIAMS determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 and FY 2013 numbers shown are actual to date.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

The primary Federal agency for conducting and supporting medical research into conditions of the bones, joints, muscles, and skin, NIAMS manages a portfolio that addresses immediate public health needs and encourages basic science research that may lead to improved health over the longer term. In 2010, the NIAMS released its Long-Range Plan for Fiscal Years 2010-2014. Like the 2006-2009 plan, the updated version is propelling research progress by informing the Institute's priority setting process, while enabling NIAMS to adapt to the rapidly changing biomedical and behavioral science landscapes.

For example, the NIAMS long-range plans influence choices about topics for annual roundtable discussions and the scientific planning retreats, which are held as part of the Institute's overall strategic planning process. These meetings, in turn, inform Institute decisions about the funding opportunity announcements that it initiates or elects to participate in.

- When NIAMS issued RFA-AR-08-001, the first NIAMS Building Interdisciplinary Research Team (BIRT) Revision Awards solicitation, "Autoimmunity – Gender and sex factors" and "Soft tissue biology – Imaging technologies" were among the combinations of disciplines mentioned. These topics relate directly to a **2007 roundtable discussion** theme, Gender and Sex Factors in Inflammation and Immune-Mediated Diseases, and a **2007 scientific planning retreat session**, Soft Tissue Imaging.
- The five **2008 roundtable discussions** to identify areas of opportunity for the 2010-2014 long-rang plan contributed to the proposal to reissue RFA-AR-10-005, the NIAMS Clinical Trial Outcome Instrument Development Program. They also prompted the Institute to release RFA-AR-11-005 and RFA-AR-11-004, NIAMS Accelerating Research Translation (ART) in Musculoskeletal and Skin Tissue Engineering and Regenerative Medicine Competitive Revision Awards—a new program to support large animal pre-clinical studies that have the potential to immediately lead to tissue engineering and regenerative medicine trials in humans.
- A discussion about the importance of Ancillary Studies to Large Clinical Projects, at the **2008 scientific planning retreat**, led to the NIAMS' new process to expedite the review and funding of time-sensitive Ancillary Studies to Large Ongoing Clinical Projects (RFA-AR-10-011 and RFA-AR-10-010; R21 and R01). It also informed BAA-NHLBI-AR-10-06, Ancillary and Complementary Research to the Osteoarthritis Initiative (OAI), which NIAMS led, and influenced the Institute's decision to participate in RFA-AI-08-011 and RFA-AI-10-014, Ancillary Studies in Immunomodulation Clinical Trials (R01).
- Following a session on Gene Therapy at the **2008 scientific planning retreat**, the NIAMS decided to encourage the small business community to explore regenerative medicine strategies, including gene therapy efforts to replace a missing or defective protein or enhance tissue regeneration. This led to RFA-AR-10-004, Translation and/or Commercialization of Musculoskeletal and Skin Tissue Engineering and Regenerative Medicine Research – SBIR (R43/R44). RFA-AR-12-006, Small Business Innovation Research on Rare Musculoskeletal, Rheumatic and Skin Diseases (R43/R44), is another initiative to come from discussions at **NIAMS retreats**.

Other initiatives arising from the Institute's strategic planning process have used solicitations other than Requests for Applications (RFAs). These include:

- PAR-08-123, Genome-Wide Association Analysis of Existing Data Sets for Arthritis and Musculoskeletal and Skin Diseases (R01) and PAR-09-135, Replication, Fine-Mapping and Sequencing: Follow-Up on Genome-Wide Association Studies for Arthritis and

Musculoskeletal and Skin Diseases (R01), which arose from discussions beginning at the **2006 scientific planning retreat**.

- Decisions to participate in PA-08-044 and PA-08-043, Human Pluripotent Stem Cell (hPSC) Research Using Non-Embryonic Sources (R21 and R01), led by NINDS, and NOT-GM-08-136, NIH Administrative Supplements for Induced Pluripotent Stem Cell Research, also were guided by a **2006 retreat session**.
- A session on epigenetics at the **2007 retreat** informed the Institute's decision to participate in RFA-RM-08-017, Epigenomics of Human Health and Disease (R01).
- PA-12-131 and PA-12-132, Improving Translational and Basic Research to Control Itch in Humans (ITCH) (R01 and R21), emerged from the **2010 roundtable on Itch Research**.

Clinical research is an essential component of the NIAMS long-range plan. In recent years, the NIAMS has assessed its support of clinical research in all of its mission areas, with the goal of maximizing the impact of NIAMS-sponsored trials, so that they will make a difference in patient care. The Institute engaged many parts of its community through discussions with its Advisory Council and at its **2009 Scientific Retreat**, as well as through a series of **Clinical Trials Roundtables** in each of the NIAMS mission areas. These efforts have resulted in a new panel of funding mechanisms to promote clinical trials development.

- PAR-10-282, Pilot and Feasibility Clinical Research Grants (R21), for example, encourages exploratory, short-term clinical arthritis and musculoskeletal and skin disease studies that are likely to gather critical, preliminary data for use in future clinical trials.
- NIAMS also launched a two-stage program of cooperative grants to support clinical trials. The first stage will be supported through PAR-11-169, NIAMS Clinical Trial Planning Grant (U34), which is mandatory before applying for PAR-11-168, the Multi-site Implementation Cooperative Agreement (UM1) or PAR-11-219, an NIAMS Clinical Trial Implementation Cooperative Agreement (U01).

Next steps

The activities described above illustrate a few of the ways that NIAMS is implementing plans to provide the American people with the best possible return on their investment. Over the next two years, NIAMS will revisit and update its long-range plan. The plan, like the previous versions, will serve as a broad scientific outline for NIAMS, and the investigative and lay communities. It will reflect significant input from extramural investigators and representatives of research societies and health voluntary organizations.

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Current Strategic Plan

The NIBIB strategic plan was last updated in 2006; however, NIBIB is currently updating its strategic plan and expects to complete the process soon.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	3	2	1	2
Contributed to by IC*	7	11	Not Available*	Not Available*

*NIBIB does not develop targets for contributing to RFAs. NIBIB determines whether to contribute to an RFA once the RFA has been developed by the lead IC.

Narrative Response:
The Strategic Plan was addressed through investigator initiated research and solicitations other than RFAs, including PA and PAR announcements.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
Numerous steps are taken on an ongoing basis to assure that Strategic Plan Goals are met. These include:

- Supporting investigator initiated research through parent program announcements
- Policies to increase the number of new investigators through differential paylines
- Solicitation for additional research to address strategic initiatives through instruments other than RFAs including PA and PAR announcements
- Workshops with scientific experts and other stakeholders to identify the most current scientific advances to inform strategies to meet goals of the strategic plan
- Working group meetings with grantees awarded through RFAs to monitor progress and to foster cross-fertilization between grantees to maximize biomedical advances and potential clinical applications of ongoing research

National Institute of Child Health and Human Development (NICHD)

Current Strategic Plans
This new scientific framework is part of a current NICHD process to develop a scientific vision that sets an ambitious agenda and inspires the Institute, its many partners, and the research community to achieve critical scientific goals and meet pressing public health needs. It will also set the stage for developing a new generation of more targeted strategic plans covering the breadth of NICHD's mission, and that include a range of specific topics or conditions. The following list represents various research plans developed by NICHD and its partners since 2007: vulvodynia (April 2012), epidemiology/ prevention (January 2010), IDD (September 2009), Fragile X (June 2009), endocrinology (June 2009), child development (January 2009), pregnancy (September 2008), contraception and reproductive health (June 2008), pharmacology (January 2008), Down syndrome (October 2007), Demographic/ Behavioral (September 2007), AIDS (June 2007), and reproductive sciences (January 2007).

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	18	26	27	16
Contributed to by IC	17	25	19*	10*

*The FY 2012 and FY 2013 targets are based on the numbers of FOAs that have been approved in the planning process to date.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

NICHD's research mission is broad -- to understand the basic mechanisms that transform cells into healthy and effectively-functioning individuals and to enhance clinical practice to prevent and ameliorate conditions that influence the lifelong health of women, children, and persons with disabilities. Thus, it takes a variety of coordinated and thoughtful planning processes and activities to identify new scientific and strategic directions in a way that enhances the stewardship of this mission.

To provide a new framework in which to update and implement previous -- and create new -- strategic plans, the NICHD recently undertook a unique "scientific visioning" process, which allowed the Institute to identify significant and emerging scientific opportunities over the next ten years. Convening multidisciplinary experts, policymakers, and leaders from advocacy groups and the private sector, the vision process allowed the NICHD to establish shared views of how and where to focus scientific efforts in eight different areas. These areas were: behavior, cognition, developmental biology, developmental origins of health and disease, environment, pregnancy, reproduction, and plasticity. Throughout the process, the Institute provided multiple opportunities for the National Advisory Council on Child Health and Human Development, as well as scientists and members of the public, to provide comments. The initial working papers are online and the final publication is expected by the end of the year.

By identifying bold ideas and future scientific directions for the next decade, the NICHD has established a new framework to guide its ongoing strategic and operational planning processes. Extramural strategic planning at the branch, trans-branch, and trans-NIH levels has allowed the NICHD to target development of specific scientific areas that can take advantage of emerging opportunities, address research gaps, and ameliorate pressing public health problems. An annual operational planning process allows for discussion and evaluation of existing programmatic efforts, assessment of new ideas, and agreement upon upcoming Funding Opportunity Announcements (RFAs, RFPs, PAs) that promote the strategic scientific goals identified through planning activities. In the past few years, increasing use of PAs, which remain in effect for three years at a time, has enabled the Institute to signal the investigator community of the Institute's strategic scientific interests over a longer period of time and grow nascent scientific areas.

These different planning processes are informed by data-gathering and consensus-building activities including scientific meetings, workshops, and conferences, and ongoing analyses of the Institute's scientific portfolio and outputs. Maintaining its focus on the importance of investigator-initiated research, the NICHD uses these tactical processes to work collaboratively with experts within and outside of the NIH to set shared research agendas, form needed partnerships, and creatively bring together resources to meet its research mission.

National Institute on Drug Abuse (NIDA)

Current Strategic Plan
The NIDA strategic plan was last updated in September 2010.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	10	10	10	9

Contributed to by IC*	2	1	6*	Not Available*

*NIDA does not develop targets for contributing to RFAs. NIDA determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 number shown is actual to date.

Narrative Response:
RFAs are not the only means by which NIDA seeks to accomplish strategic goals. In fact, the majority of NIDA-supported research stems from investigator-initiated grants focusing on specific areas in which NIDA has expressed interest (see below).

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
Examples of tactical approaches that NIDA uses to implement strategic priorities include the following:

1. **Use of mechanisms other than RFAs.** As stated above, the majority of NIDA-supported research stems not from RFAs, but from investigator-initiated grants focusing on a broad range of topics relevant to NIDA's mission. To assist this, NIDA issues program announcements that highlight areas of scientific interest, which do not have funds set-aside as do RFAs. NIDA staff also organizes workshops and symposia to identify gaps in the science, and stimulate research in specific areas related to the Strategic Plan.
2. **Use of infrastructures.** NIDA has established two large community-based, multisite infrastructures–The National Drug Abuse Clinical Trials Network (CTN) and Criminal Justice–Drug Abuse Treatment Studies (CJ-DATS) initiative–to test evidence-based interventions and how best to implement them in "real-world" settings. These infrastructures allow NIDA-supported researchers to test promising drug abuse interventions in the populations who most need them, working on-site with community treatment providers and other collaborators to determine treatment feasibility and practicality and promote their adoption.
3. **Strategic partnerships.** To advance NIDA's strategic goals, NIDA collaborates with multiple partners, which facilitates the uptake of evidence-based drug abuse prevention and treatment interventions and broadens the impact of NIDA's efforts. Examples of partnerships include those with:
    - the criminal justice system to promote medication-assisted treatment for drug abuse and screening and early intervention for those who test positive for HIV;
    - pharmaceutical companies to help shoulder the costly process of developing medications for addiction (only a handful of which exist);
    - other Federal entities, including the Surgeon General, the White House (Office National Drug Control Policy), and other HHS agencies, with whom NIDA is preparing to launch a Surgeon General's document to prevent prescription drug abuse among youth, as part of a multiagency collaborative effort; and
    - youth to engage them with NIDA's anti-drug/pro-health messaging and as "ambassadors" to spread the word via new media and other peer-to-peer communications.
4. **Enlisting experts in evaluating progress and focusing efforts.** To stay abreast of the most beckoning areas of research need, NIDA routinely assembles workgroups comprised of NIDA council members and diverse outside experts to evaluate NIDA programs and recommend to the Director how NIDA could best respond to urgent public health needs and

simultaneously build a strong scientific infrastructure. Such workgroups have focused on many different subjects over the years, including HIV/AIDS, health services research, medications development, prevention research, science of genetics, translation of evidence-based treatments, and minority health disparities.

5. **Dissemination efforts.** A major aspect of NIDA's mission, also reflected in NIDA's Strategic Plan, is to "ensure the rapid and effective dissemination and use of the results of our research to significantly improve prevention and treatment and to inform policy as it relates to drug abuse and addiction." To this end, NIDA has created several productive initiatives to reach multiple audiences with diverse information about drug abuse and addiction. Examples include:
   - NIDAMED, NIDA's physician outreach initiative, to provide online tools and resources to help physicians screen for substance abuse in their practices. NIDA has been expanding this initiative to further address some of the barriers primary care and other clinicians face, such as a lack of resources, lack of training, and personal biases when treating patients with drug abuse problems.
   - NIDA's Blending Initiative—a collaboration between NIDA and SAMHSA to develop research-based "products" and to train treatment providers in their use. "Blending" aligns with NIDA's strategic priorities to accelerate the adoption of evidence-based practices into medical settings and drug abuse treatment programs by helping ensure that treatments showing positive results are practical, that they align with community and provider needs and values, and that they are accepted and used by practitioners.
   - NIDA for Teens Website. NIDA has expanded its highly successful website, adding a *PEERx* (http://teens.drugabuse.gov/peerx/choose-your-path/) educational tool to provide teens with information about prescription drug abuse and to encourage them to interact with other teens in a positive way. NIDA also continues to provide regular updates to the highly successful Sara Bellum Blog and to respond to posted comments from its mainly teen audience. The interactivity of these sites underlies their success for message dissemination.
6. **Outreach to other stakeholders.** These include substance abuse researchers and practitioners in the field, State substance abuse treatment and prevention directors, and a variety of constituent groups. Meetings with constituent groups offer opportunities both to share NIDA's latest research results and to receive input on NIDA's research priorities. Through a diverse outreach process, NIDA "seeds" ideas for further research needs, which are then fed back into NIDA's strategic planning process via Council membership, constituent groups, and Institute staff, creating an instructive feedback loop that ensures inclusion of emerging needs in NIDA's calls for research and training priorities.

National Institute on Deafness and Other Communication Disorders (NIDCD)

Current Strategic Plan
The NIDCD strategic plan was last updated in January 2012.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	4	4	3	1
Contributed to by IC*	6	12	6*	Not Available*

*NIDCD does not develop targets for contributing to RFAs. NIDCD determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 number shown is actual to date.

Narrative Response:
NIDCD does not issue a predetermined number of RFAs each year. The Institute issues an RFA if NIDCD staff determine that there is an area of unmet scientific need (i.e., the investigator-initiated applications have not addressed this topic or area) that can only be met by encouraging research applications via an RFA. As NIDCD staff develops RFAs, we may state if they are in response to a goal from the strategic plan. NIDCD can also encourage applications relevant to goals in our strategic plan via other types of Funding Opportunity Announcements, such as Program Announcements.

The Institute places a high priority on investigator-initiated research proposals, and prefers to meet its goals via funding of investigator-initiated grants that receive meritorious scores in the peer review system whenever possible. Once the most highly rated projects are funded, NIDCD staff and National Deafness and Other Communication Disorders (NDCD) Advisory Council members use the strategic plan to identify applications for High Program Priority (HPP). HPP grants are those that received good reviews but do not fall within the automatic payline, yet are important for the NIDCD to accomplish its goals. NIDCD uses the HPP process to identify and fund these important research opportunities.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
The NIDCD Strategic Plan (Plan) is a guide for the Institute (including NIDCD staff and the NDCD Advisory Council) to prioritize research investment. The NIDCD uses the Plan as a tool when nominating investigator-initiated research applications for HPP funding, and when developing Funding Opportunity Announcements (FOA). Furthermore, NIDCD staff makes the plan available to researchers and the public by posting it on the NIDCD webpage. NIDCD staff also distributes the Plan to the research community at workshops or research conferences to increase awareness of Institute priorities. Investigators may submit applications for research projects that directly address priorities within the Plan. Finally, the Plan informs the public about the state of the science and advances in diagnosis and treatment of communication disorders, while sharing the NIDCD vision for the future.

In order to track and evaluate our research portfolio, the NIDCD compares funded research projects each year to the priority areas in the Plan. The NIDCD staff analyzes the research portfolio to demonstrate how well the funded NIDCD research portfolio corresponds with the Plan's priority areas and other designated trans-NIH needs or priorities. NIDCD and the NDCD Advisory Council then assess the level of emphasis in the portfolio and/or identify research gaps.

The NIDCD believes that the scientific merit of a grant application, as judged by initial peer review, is the single most important criterion in the determination of funding. As evidence, 80% of the funds available at each NDCD Advisory Council meeting are used to support grants of the very highest technical merit, independent of discipline or NIDCD program area. The remaining 20% of funds are used to support additional meritorious applications designated as HPP and nominated by NIDCD program staff and approved by the NDCD Advisory Council based on the following HPP nomination criteria: to fill scientific gaps or deficiencies in the grant portfolio

(including meritorious applications in areas identified as priorities in the Plan), to foster the entry of new investigators into the field, to foster innovative research, and to increase the diversity of principal investigators and grantee institutions in the portfolio.

National Institute of Dental and Craniofacial Research (NIDCR)

Current Strategic Plan
The NIDCR strategic plan was last updated in February 2009.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	9	3	8	6
Contributed to by IC	3	1	2	1

Narrative Response:
The number of RFAs funded in a given year reflects a range of variables, and the need to move certain scientific fields forward to expand knowledge and improve health must be balanced over a multi-year period with the readiness of the field, ripeness of the scientific opportunity, budgetary flexibility, and recent distribution of funding opportunities.

It is important to emphasize that traditional R01 grants remain the lifeblood of the Institute's research portfolio, and are fundamental to achieving our mission. NIDCR is able to achieve a balance that encourages investigators to steer their energies in directions that correspond with our priorities as described in our strategic plan while encouraging discovery research where investigators are exploring outer boundaries of existing understanding.

In addition to using Requests for Applications (RFA) to "steer" investigators towards particular research areas, NIDCR use a variety of tools beyond RFAs, including Program Announcements (PAs), scientific conferences and workshops to assess research needs, and to catalyze research in high priority areas to ensure the Institute's goals and priorities are met.

NIDCR also leverages the expertise of our scientific program officials in making sure our research portfolio reflects our strategic plan. In making funding decisions, we carefully weigh scientific merit as judged by the first level of peer review, while giving consideration to the need to fill significant scientific gaps in the Institute's research portfolio, the alignment with our stated strategic goals, potential scientific overlap with grants already supported, whether the applicant is a new investigator, and the level of other support available to the applicant. To assist in this, NIDCR maintains a modest discretionary pool of funds used to support applications falling outside the pay line that the Institute determines should be funded for programmatic reasons as previously described.

Our strategic plan enhances the Institute's ability to recognize tactical opportunities for partnership. For example, we support the Specialized Programs of Research Excellence (SPORE) for Head and Neck Cancer in partnership with the NCI, enabling a wide range of projects in prevention, early detection, diagnosis, prognosis, and therapy of head and neck cancer patients.

Finally, it is important to note that NIDCR leadership employs several strategies to ensure that intramural projects are also aligned with NIDCR's mission and Strategic Plan, including internal administrative funding decisions and an external review by the Board of Scientific Counselors, an advisory committee focused on intramural activities. The Intramural Research Program supports projects that complement the extramural portfolio of dental, oral, and craniofacial research and addresses our strategic planning goals, ultimately improving the Nation's oral health.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

The NIDCR remains committed to improving the oral, dental and craniofacial health of our nation. As we prioritize among competing research opportunities through the development and implementation of the strategic plan, we are mindful that the ultimate goal of our scientific efforts is to improve people's lives. The 2009-2013 NIDCR Strategic Plan is built on four key goals: widening our scope of inquiry, strengthening the research pipeline, fostering novel clinical research avenues, and eliminating oral health disparities. This Plan creates a framework within which high-quality research addressing important oral health problems can be organized, communicating priorities to the extramural community. Simultaneously, it allows for sufficient scientific innovation that newly emerging areas of discovery are not overlooked, and affords the opportunity for outside experts to weigh in on our current and future directions.

NIDCR has taken a number of tactical steps to implement the 2009-2013 NIDCR Strategic Plan:

- The 2009-2013 NIDCR strategic planning process gathered public and stakeholder input about prospective activities, areas of research emphasis, future research approaches, needs, and opportunities. The engagement of these key stakeholders in developing the Strategic Plan led to an enthusiastic embrace by the research community of the priorities that were ultimately identified through this process.
- NIDCR made active efforts to disseminate the strategic plan in order to communicate our identified goals, including distributing the plan in hard copy, making it easy to download electronically, as well as ensuring that the goals outlined in the Strategic Plan are reflected in presentations by the NIDCR Director and senior staff at national and international meetings, as well as our communications with Congress and other stakeholders.
- In addition to making the plan easily accessible, NIDCR is increasingly providing an explicit link to the Strategic Plan in concept clearances and funding opportunity announcements.
- NIDCR also uses the Strategic Plan as a guide for our annual planning process for developing funding opportunity announcements, and links projects to Strategic Plan goals and objectives when making funding decisions. For example, the Strategic Plan guided our decision-making for allocating funds that were made available via the American Recovery and Reinvestment Act (ARRA). Resulting investments in specific areas such as behavioral and social science, health disparities, clinical validation of salivary biomarkers, and a comprehensive genetic profile of oral and pharyngeal cancer reflect specific areas highlighted in our Strategic Plan. NIDCR investigators have developed promising candidate compounds based on the body's own inflammation-resolving molecules and will be moving these compounds into human studies within the next year to evaluate their safety and efficacy in turning off the destructive inflammation occurring in periodontal disease, and NIDCR is currently supporting aggressive efforts to provide clinical validation of salivary biomarkers that, if validated, could provide a self-contained, portable diagnostic test for

diseases including cardiovascular disease and oral cancer. In this process, the plan helped to better organize investments and further the goals and objectives of our Strategic Plan.

Finally, NIDCR is completing a comprehensive evaluation of our strategic plan. This effort includes portfolio reviews and analysis of our research programs, as well as an assessment of the satisfaction of stakeholders with the Strategic Plan, and the utility and value of the plan internally at NIDCR and within the extramural science community. We intend to use this information to inform the process for developing the 2014-2018 NIDCR Strategic Plan, which will launch in the fall of 2012.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Current Strategic Plans

Because of the diverse nature of NIDDK's mission, the Institute has found it to be most effective to focus on disease-specific, organ-specific, or program-specific strategic planning. Examples of NIDDK's strategic plans, along with the dates they were published/last updated, are included below:

- Advances and Emerging Opportunities in Diabetes Research: A Strategic Planning Report of the Diabetes Mellitus Interagency Coordinating Committee – published February 2011.
- Advances and Emerging Opportunities in Type 1 Diabetes Research: A Strategic Plan – published August 2006. This plan was updated in part by the 2011 diabetes strategic plan listed above; NIDDK uses both plans for type 1 diabetes research strategic planning.
- Strategic Plan for NIH Obesity Research – originally published in 2004. The updated version was published in March 2011.
- Opportunities and Challenges in Digestive Diseases Research: Recommendations of the National Commission on Digestive Diseases – published March 2009.
- Trans-NIH Action Plan for Liver Disease Research – published December 2004. Major research goals in this plan were incorporated and updated in the 2009 research plan of the National Commission on Digestive Diseases (listed above).
- NIDDK Prostate Research Strategic Plan – published May 2008.
- NIDDK Research Progress Report and Strategic Plan for Pediatric Urology – published February 2006.
- Overcoming Bladder Disease: A Strategic Plan for Research – published August 2002.
- Renal Disease Research Plan – published in 1999. A new planning effort is under way to identify current opportunities in kidney disease research.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC*	12	23	21	Not Available*
Contributed to by IC**	3	8	Not Available**	Not Available**

*The FY 2013 estimate is still to be determined because of budgetary issues related to the Special Statutory Funding Program for Type 1 Diabetes Research, which NIDDK administers on behalf of the Secretary, HHS, and in collaboration with other NIH components and the CDC. The Program is a special appropriation separate from the regular NIH appropriation and it is limited in time. It has been extended several times since its inception and is currently set to expire at

the end of FY 2013. RFA numbers for FY 2007, FY 2011, and FY 2012 include initiatives supported by the Special Diabetes Program. Because the Program is set to expire in FY 2013, no new initiatives for this Program would be issued in FY 2013. However, if the Program is extended beyond FY 2013, the NIDDK anticipates issuing additional RFAs to solicit new research applications. Those new initiatives would be guided by diabetes strategic plans (see above), as well as by obtaining broad external input at venues such as workshops, scientific conferences, and planning and evaluation meetings.
**NIDDK does not develop targets for contributing to RFAs. While NIDDK may provide input to another IC during RFA development, NIDDK determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
The NIDDK uses multiple approaches to implement its strategic plans. The Institute reviews the opportunities identified in the strategic planning processes to inform the development of research solicitations, such as RFAs and Program Announcements, which then go through concept clearance in public meetings. To promote the strategic plans and encourage grant applications in areas identified in the planning processes, NIDDK announces the strategic plans and posts them on the Institute's website, for broad sharing with the research community. NIDDK also funds investigator-initiated research on diseases within its mission and relevant to the opportunities and priorities identified in strategic plans. The Institute collaborates with and gains input from other NIH ICs. NIDDK also obtains external input from researchers, organizations, other Federal agencies, and others by convening scientific conferences and workshops. Through these meetings, NIDDK assesses the state-of-the science; reviews progress; and identifies challenges, research gaps, and opportunities for new research directions to meet planning goals. In an ongoing planning effort, NIDDK is using social media to interact with the research community and others to identify research opportunities. These efforts ensure that the strategic planning process remains dynamic, so that NIDDK can build on research discoveries and pursue promising avenues to maximize the public investment in research on the many diseases within the Institute's mission.

National Institute of Environmental Health Sciences (NIEHS)

Current Strategic Plan
The NIEHS strategic plan was last updated in 2006. However, NIEHS is currently undergoing a strategic planning process, and expects to finalize the new plan in June 2012.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	5	11	4	8
Contributed to by IC*	10	16	9*	Not Available*

*NIEHS does not develop targets for contributing to RFAs. NIEHS determines whether to contribute to an RFA once the RFA has been developed by the Lead IC. The FY 2012 number shown is actual to date.

Narrative Response:

FY 2011 was the last full year for which research solicitation planning was governed by our 2006 Strategic Plan. In February 2011, NIEHS began the process of developing a new Strategic Plan. The reduction in NIEHS-led RFAs in FY 2012 compared to FY 2011 reflects the fact that our new Plan is not yet finalized. Once the new Strategic Plan is finalized (expected June 2012) NIEHS expects to move forward with solicitations to address its updated goals, starting in FY 2013.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

- NIEHS has expanded its Global Health Program through hiring additional personnel, initiating new projects, and being part of the Global Research Initiative Program, Behavioral/Social Sciences.
- NIEHS established an onsite Clinical Research Program to more fully develop the role of clinical research in environmental health sciences.
- In an effort to further develop sensitive markers of environmental exposure, early (preclinical) biological response, and genetic susceptibility, NIEHS has initiated program announcements in detection of gene-environment interactions and support for cutting-edge nano-science and nanotechnology research.
- NIEHS has taken steps to develop new exposure technologies through Small Business funding opportunities that develop, standardize, and validate new and innovative assays, integrated strategies, or batteries of assays that determine or predict disease from environmental exposures.
- NIEHS has funded R&D projects that will further our understanding of how environmental toxicants influence basic mechanisms in human biology, such as characterizing the potential toxicity and carcinogenicity of cell phone radio frequency radiation.
- In addition, NIEHS established a collaboration with EPA and FDA to develop and validate chemical testing methods that characterize toxicity pathways that will also better predict how chemicals affect biological responses.

National Institute of General Medical Sciences (NIGMS)

Current Strategic Plan

The NIGMS strategic plan was last updated in January 2008. The strategic plan for training was last updated in 2011.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	6	11	8	3
Contributed to by IC*	9	0	Not Available*	Not Available*

*NIGMS does not develop targets for contributing to RFAs. NIGMS determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Narrative Response:

The number of RFAs listed has decreased for several reasons: (1) NIGMS issues RFAs to catalyze science in specific areas. Once this occurs, investigator initiated research becomes the norm. (2) our total portfolio from one year to the next contains prior year RFAs which are not captured

above; and (3) NIGMS continues to make adjustments to its funding priorities based on new scientific opportunities. NIGMS considers the variation in RFAs, dependent on funding as well as scientific developments, to be a normal cycle. Historically, NIGMS continues to view the investigator -initiated R01 to be the primary mechanism by which the institute has funded basic research. The percentage of NIGMS's budget going to R01 research has remained constant.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
As NIH's "basic research institute," NIGMS continues to support research seeking to answer important scientific questions in fields such as cell biology, biophysics, genetics, developmental biology, pharmacology, physiology, biological chemistry, biomedical technology, bioinformatics, computational biology, selected aspects of the behavioral sciences, and specific cross-cutting clinical areas that affect multiple organ systems. NIGMS plans to maintain its strategy of supporting investigator-initiated research providing a broad foundation of discovery. Also, a key goal of our strategic plan is to facilitate the development of a diverse and inclusive biomedical research workforce. To this end, NIGMS has recently established a new organizational component, the Division of Training, Workforce Development, and Diversity, which integrates training and diversity activities across Institute programs. In addition, the Institute recently issued a strategic plan for training with an accompanying implementation plan. (http://www.nigms.nih.gov/Training/StrategicPlanImplementationBlueprint.htm)

National Institute of Mental Health (NIMH)

Current Strategic Plan
The NIMH strategic plan was last updated in August 2008.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	0	5	4	7
Contributed to by IC*	0	0	Not Available*	Not Available*

*NIMH does not develop targets for contributing to RFAs. NIMH determines whether to contribute to an RFA once the RFA has been developed by the Lead IC.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
After the 2008 launch of NIMH's Strategic Plan, the Institute initiated an implementation process to identify research opportunities and prioritize investments consistent with the broader objectives outlined in the Plan. NIMH created four Strategic Objective working groups composed of program and policy staff from across the Institute. Each group was asked to focus on one of the Plan's four Strategic Objectives. These groups meet regularly to discuss research advancements in their respective fields and identify key, addressable research topics stemming from the Strategic Plan. The groups, in collaboration with NIMH's senior leadership, select topics that serve as the basis for future funding opportunity announcements.

NIMH monitors its investments in relation to the Strategic Plan through periodic portfolio analyses. Each research Division also analyzes its incoming applications to see how they

correspond to the Strategic Plan's Objectives and Strategies. The results from these analyses are used to track the balance of funding across NIMH's portfolio and to inform funding decisions.

The 2008 Strategic Plan was envisioned to guide the Institute's funding decisions for 5 years. NIMH is in the initial phases of developing its next strategic plan.

National Institute on Minority Health and Health Disparities (NIMHD)

Current Strategic Plan
The NIMHD strategic plan was published in 2012.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	3	8	5	6
Contributed to by IC	1	12	6	4

Narrative Response:
Grant awards made in response to RFAs issued in FY 2011 had 5-year project periods and renewal cycle is outside of FY 2012 and FY 2013.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

- Issued FOAs to support the priorities under the health disparities research, capacity building, and outreach goals.
- Sponsored monthly NIH-wide Health Disparities Seminar Series.
- Conducted an annual NIMHD Translational Health Disparities Course.
- Convene a 2012 Summit on the Science of Eliminating Health Disparities: Integrating Science, Practice, and Policy.

National Institute of Neurological Disorders and Stroke (NINDS)

Current Strategic Plan
The NINDS strategic plan was last updated in June 2010.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC*	3	14	7	Not Available*
Contributed to by IC*	15	18	13	Not Available*

*NINDS does not have a target number of RFAs (or any solicitations) for FY 2012 or FY 2013. The FY 2012 figures in the table include the number of RFAs that have been issued so far this year.

Narrative Response:
NINDS does not have a target number of RFAs (or any solicitations) for FY 2012 or FY 2013. In general, NINDS uses multiple types of initiatives (in addition to RFAs) as well as other actions to

implement planning priorities, and the specific types, size of investment, and numbers of solicitations used will vary depending on the priorities being addressed. For example, the Institute designs individual solicitations in priority areas such as translational and clinical research to serve needs across multiple diseases, rather than issuing separate solicitations for each. This strategy allows NINDS to retain maximum flexibility in implementing priorities and responding to scientific opportunities as they arise.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases
NINDS completed its most recent strategic planning process in 2009 and released a summary report in June 2010 that incorporated input from expert working groups, the National Advisory Neurological Disorders and Stroke (NANDS) Council, and the research and patient advocacy communities. The planning effort focused on practical strategies for improving the Institute's effectiveness in supporting and advancing basic, translational, and clinical research across the broad spectrum of neurological diseases within the NINDS mission. The resulting plan recognized that science can advance rapidly and in unexpected ways. While emphasizing the importance of investigator-initiated, peer-reviewed research as the foundation of the NINDS basic research program, the plan provides guidance on how the NINDS should set priorities in order to facilitate and help direct new discoveries. The plan also highlights key scientific opportunities for progress likely to yield benefits across many neurological disorders.

NINDS has taken many steps to implement recommendations and achieve goals in accordance with this strategic plan. For example, the NINDS Office of Translational Research, led by an Associate Director with extensive drug development experience, is taking a more active and better coordinated approach to managing translational research. Among other activities, the Office of Translational Research is leading a Grand Challenge for New Drugs for Diseases and Disorders of the Nervous System, in collaboration with 15 other NIH Institutes and Centers that work together through the NIH Blueprint for Neuroscience. The goal of this ambitious program is to support the development of new small molecule drugs that will transform the treatment of neurological, psychiatric, or other nervous system diseases or conditions. In addition, to address a recommendation to use the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs more effectively, NINDS consolidated its previously distributed small business grants portfolio within the Office of Translational Research and assigned dedicated staff with business expertise to manage the portfolio, enhance outreach, and promote the commercialization of products and services developed through these programs.

Several planning recommendations focused on improving the efficiency of clinical research and helping to ensure that NINDS invests in clinical research with the greatest potential to reduce the burden of neurological disease. Because of their large size and long duration, Phase III clinical trials are complex and challenging to design and implement, and despite careful planning, they can suffer delays due to slow patient recruitment, regulatory issues, or other factors. To prioritize support for trials likely to be completed successfully, the NINDS Office of Clinical Research is implementing a new policy that makes continued funding contingent on feasibility milestones. Through a new initiative, NINDS supports a clinical trials network for early stage clinical trials and research studies (NeuroNEXT: Network for Excellence in Neuroscience Clinical Trials), which aims to provide a shared infrastructure for the rapid development of

research protocols and build and organize a cadre of investigators who can implement studies efficiently.

NINDS is also supporting research to address scientific opportunities highlighted in the NINDS Strategic Plan, including the development of biomarkers and research consortia focused on specific diseases. For example, the new NINDS Epilepsy Centers without Walls program supports multidisciplinary consortia to solve specific challenges in the prevention, diagnosis, or treatment of the epilepsies. The first awarded Center aims to identify new genes and genetic pathways that contribute to common forms of epilepsy by analyzing 4,000 genomes of epilepsy patients and families collected by several major research groups. The program also provides support for planning grants toward future Centers focused on other challenges in epilepsy research. As another example, in collaboration with the NIH Office of Rare Disease Research, NINDS supports many consortia within the NIH Rare Diseases Clinical Research Network and administers the network's coordinating center. In terms of biomarker development, NINDS recently announced the Parkinson's Disease Biomarkers Program (PDBP), which aims to identify and develop potential biomarkers to advance therapeutic development for Parkinson's disease. In addition, the first research study supported through NeuroNEXT will focus on the development of biomarkers for spinal muscular atrophy.

Overall, as the NINDS undertakes targeted initiatives and programs to meet changing opportunities, the Institute must evaluate their outcomes and seek to maintain a balance of basic, translational, and clinical research that maximizes the Institute's impact on public health. In response to recommendations from the planning process, the NINDS has established an internal working group to track the Institute's investments across the spectrum of research and to explore the potential impact of new policies and initiatives on portfolio balance. This group has also led internal evaluations of NINDS programs, including efforts that have led to revised policies for research resources support and the use of specific funding mechanisms.

National Institute of Nursing Research (NINR)

Current Strategic Plan
The NINR strategic plan was last updated in October 2011.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC*	2	5	5	4*
Contributed to by IC**	7	11	6*	Not Available**

*This represents a preliminary number: FY 2013 RFAs will be finalized after review by the National Advisory Council for Nursing Research in September 2012.
**For non-lead RFAs, NINR awaits the release of RFAs (by the lead IC's) to all NIH-IC's for consideration. NINR assesses the match for each non-NINR-led RFA to NINR's strategic priorities and available budget. The FY 2012 number is actual to date.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

Commensurate with the National Institutes of Health's longstanding commitment to maximizing the public investment in improving the Nation's health, the National Institute of Nursing Research (NINR) engages strategic planning in the development and assessment of its research portfolio. At all phases of research development, NINR uses its Strategic Plan to communicate its priorities to the scientific community, highlighting the critical areas of public health research in which needs are most acute and for which the Institute can make its greatest impact. In addition, careful strategic planning enhances NINR's ability to evaluate its past and current activities, monitor emerging research trends and public health needs, and adapt to the ever-changing research environment as circumstances dictate.

In October 2011, NINR commemorated its 25th Anniversary and took the opportunity to reflect on past accomplishments and future priorities for supporting research and training nurse scientists, with the ultimate goal of improving the Nation's health. The culmination of NINR's 25th Anniversary year marked the launch of the Institute's new strategic plan, *Bringing Science to Life*, which will guide NINR's priorities in the coming years. A key focal point of the strategic plan is the "science of health," which focuses on the promotion of health and quality of life. This document is available for download on the NINR website and has been widely disseminated to the research community.

NINR will seek to advance the science of health by: enhancing the management of symptoms of chronic illness by engaging individuals as active participants in their own health and by improving clinical management of illness; designing culturally-appropriate interventions to prevent illness in diverse groups, promote health equity, and eliminate health disparities; improving quality of life for those with advanced illness by advancing evidence-based palliative and end-of-life care; developing new technologies and innovative programs to improve health while at the same time containing health care costs, and; equipping the next generation of nurse scientists and nurse clinicians with the skills needed to meet both current and future health challenges and improve health care.

While, like other NIH ICs, the majority of the NINR research portfolio consists of projects conceived and proposed by individual investigators, NINR uses RFAs to target specific types of research when tightly circumscribed programmatic objectives need to be met. The development of research initiatives, including RFAs, at NINR is a 24-month process that involves scientists from every branch and office within NINR, and is overseen by the NINR Director and experts that comprise the National Advisory Council for Nursing Research. This rigorous process of research, collaboration and review ensures that initiatives are put forward that are directly related to the Strategic Plan and that they are highly relevant to the health of the Nation.

The Nation faces complex health care challenges which require new ways of thinking and new models of care. To address these issues, consistent with the goals outlined in its Strategic Plan, NINR's research programs will continue to incorporate a broad range of interdisciplinary approaches designed to promote scientific exploration leading to better health outcomes and health services. NINR will also maintain its strong commitment to addressing the health needs of minority and underserved populations and to building a diverse scientific workforce.

National Library of Medicine (NLM)

Current Strategic Plan

The NLM strategic plan was last updated in September 2006.

RFAs issued that identified specific research themes to achieve strategic goals.

# of RFAs	FY 2007 Baseline	FY 2011 Actual	FY 2012 Target	FY 2013 Target
Led by IC	0	2	1	1
Contributed to by IC*	0	4	2*	1

*The FY 2012 number shown is actual to date.

Narrative Response:
The number of RFAs is not increasing due to a greater emphasis accorded to preserving research grant funds for investigator-initiated research, which history shows to fit our strategic plan priorities very well. One of our tactics is to publish research priorities in our research grant Program Announcement "NLM Express Research Grants in Biomedical Informatics" and put language on our web site that guides people to that list of priorities for funding announcements that do not otherwise have them.

The fact that there are 2 NLM-led RFAs in 2011 is due to the NLM training program competition, which is only held every 5 years. Otherwise, the number would have been steady at one RFA per year.

Summary of the tactical steps taken to implement the strategic plan to maximize the significant public investment with the ultimate aim of curing diseases

1. A Eureka RFA GM 09-008 (joint with NIGMS but with specific NLM topics) issued in 2008 resulted in 6 awards made with ARRA funds in 2009. Appropriated funds were not provided for more than 2 of these. The Eureka topics were also incorporated into the NIH Recovery Act Challenge Grants, and the SBIR/STTR parent award topics. This relates to the goal on representation, interpretation, and use of biomedical knowledge in electronic forms.
2. Building on the 2008 experience, NLM issued RFA LM 11-002, Advanced Informatics for Health with a clinical topic relating to consumer health information. Two awards are being made in FY 2012. We currently plan to reissue it in 2013 with a new topic. This relates to the goal on representation, interpretation, and use of biomedical knowledge in electronic forms.
3. A unique NLM Resource grant program was converted to an RFA in 2010, with focus on information resources for health disparities, and with emphasis on participation by health science libraries and minority serving organizations. Four awards were made in FY 2011. This RFA has been issued again in 2012. This relates to the goal on reduction of health disparities.
4. NLM's institutional informatics research training programs are renewed every 5 years via RFA. The most recent RFA was issued as LM 11-001, with 14 awards to be made in FY 2012. A notice of intent was published to alert the community of the upcoming RFA, and a webinar was held to provide technical assistance to interested parties. This relates to the goal on education for biomedical informatics.
5. At this time, based on the President's Budget request, we plan to re-issue the Advanced Informatics for Health RFA in 2013. The 2013 RFA target is predicated on issuing this RFA.

Office of AIDS Research (OAR)

OAR (http://www.oar.nih.gov/) has unique legislative authorities unlike any other NIH entity to plan, coordinate, evaluate, and budget the entire NIH AIDS research program. AIDS research is carried out by all of the NIH Institutes and Centers (ICs) in accordance with their mission, in both intramural and extramural programs. This diverse research portfolio demands an unprecedented level of trans-NIH scientific coordination and management of research funds. OAR serves as a model of trans-NIH planning and management, operating as an "institute without walls," allowing NIH to pursue a united research front against the global AIDS epidemic.

Each year, OAR develops the *Trans-NIH Plan for HIV-Related Research* (http://www.oar.nih.gov/strategicplan/). The Plan is developed in collaboration with scientists from the NIH ICs, other government agencies, and non-governmental organizations, as well as community representatives. During the planning process, the state of the science is reviewed, newly emerged and critical public health needs are assessed, and scientific opportunities are identified. The annual process culminates with the identification of the highest strategic priorities and critical research needs. The Strategic Plan is a unique and critical document, as it serves as the framework for: developing the annual AIDS research budget for each IC; determining the use of AIDS-designated dollars; developing the annual By-Pass budget to the President; and tracking and monitoring all NIH AIDS research expenditures.

OAR is mandated by statute to develop the annual trans-NIH AIDS research budget in partnership with the ICs and explicitly tied to the objectives of the Strategic Plan. The ICs submit their AIDS-related research budget requests to OAR, presenting proposed new, expanded, or recompeting program initiatives, coded to specific Plan objective(s). OAR reviews the IC initiatives in relation to the Plan, its priorities, and to other IC submissions to eliminate redundancy and/or to assure cross-Institute collaboration. Dollars are allocated by OAR to the ICs based on the priorities of the Plan, scientific opportunities, and the IC's capacity to absorb and expend resources for the most meritorious science – not on a formula. At the time of the appropriation, OAR informs each IC of its AIDS-related budget allocation, specifying amounts for each approved initiative.

OAR also implements the Plan by managing and facilitating multi-Institute and trans-Institute activities to address the Plan's priorities. OAR fosters this research through a number of mechanisms, such as designating funds and supplements to jump-start or pilot program areas and sponsoring reviews or evaluations of research program areas to identify research needs.

7) **Please explain the specific lessons learned from the NIH and SMRB approach to the development of NCATS and describe what changes are being made to the SMRB process and how the lessons learned will impact future reorganization requests in future budget requests.**

Answer: NIH commends the SMRB on its thorough and deliberative approach in undertaking the complex issues it has considered to date, such as those detailed in its Report on Deliberating Organizational Change and Effectiveness. The SMRB's deliberations on the optimal organization of translational medicine and therapeutics programs at NIH reflected the Board's commitment to transparency throughout its deliberative the process. Both NIH and the SMRB are confident

that the processes employed to date were sound and aimed at improving the agency's ability to fulfill its mission. SMRB will continue to strive to meet the highest standards in formulating its advice, in gathering diverse perspectives, and in maintaining the transparency of its work. The NIH Director regards the SMRB to be a valuable source of independent advice on the agency's organization and management.

With regard to any future reorganization that the agency may propose based on SMRB recommendations, NIH will take the necessary steps to plan for effective implementation. For example, after carefully reviewing the SMRB recommendations regarding substance use, abuse, and addiction-related research, which were based on the Board's full consideration of the budgetary and operational consequences, the history of NIH's investment, and implementation costs, challenges, and impacts, NIH concluded that a new Institute solidified around substance use, abuse, and addiction-related research would help optimize the organization and management of this important research and capitalize on existing and potential synergies. As part of implementation planning for this reorganization proposal, NIH has convened an internal task force to analyze which existing research portfolios should be included in the new Institute and a planning committee composed of scientific experts is developing a strategic plan. We have also engaged with the public and stakeholder communities through a webinar and gathered public perspectives through a Request for Information, which, to date, has generated over 140 comments.

8) We understand the Cures Acceleration Network (CAN) authority requires the establishment of the Board and adoption of a plan before any projects can be started. Please provide an update on the creation of the board and spend plan timeline for the funds provided in FY 2012 toward potential board approved activity. Please identify when the Committee should expect to receive the general principles and measurable objectives from the CAN Board. Please provide an update on the status and timing of the IOM report requested for the CAN Board.

Answer. The National Center for Advancing Translational Science (NCATS) is focusing on the analysis and development of models to facilitate the commercialization of federally funded basic and applied research discoveries and on research that will help "de-risk" the drug development process. A number of stakeholder outreach activities are underway to identify and develop models of innovative public-private sector collaborations to speed therapeutic development. For example, meetings held with industry, academia, and the Food and Drug Administration in the last year culminated in the establishment of a collaboration to speed the commercialization of therapies by finding new uses for existing molecules and drugs. In early May 2012, NIH announced a new collaborative program between the biomedical research community and pharmaceutical company partners to explore new uses for discontinued proprietary drug candidates across a broad range of human diseases. A key element of the program incorporates innovative template agreements designed to streamline the legal and administrative process for participation by multiple organizations. These template agreements reduce time, cost, and effort, as well as allow greater participation than traditional partnerships. The program is also designed to leverage the expertise and innovative ideas of the entire U.S. biomedical research community. The discoveries that emerge from this program could be commercialized by the participating companies or third-party companies around the country.

Another example is the effort underway to establish a consortium of scientists in industry, academia, and government to work together to improve the validation of targets for drug development which is another significant challenge in the therapeutic development process. There is growing recognition on the part of industry of the value of collaboration in leveraging the knowledge, strengths, and expertise of multiple sectors, and the meeting will bring together invited participants from industry, academia, and government to plan pre-competitive collaborative projects, including projects focused on cancer, that will integrate the best available science into a more harmonized approach to target validation. These projects will be open to, and in many cases, call for the participation of a wide range of academic and industry participants. Improving how scientists approach target validation and enhancing the target validation process will help de-risk an important step in the product development pipeline and increase our overall ability to translate new discoveries into clinically useful products.

As these examples demonstrate, NIH's approach is to identify and design collaborative models to tackle specific strategic areas such as promoting drug rescue through industry-research community partnerships and using a consortium approach to leverage scientific knowledge to improve target validation. Certainly, NIH does not have a monopoly on innovative collaborative approaches, and NCATS will continue to engage with stakeholders to identify other models that have emerged in the marketplace and to consider how current NIH mechanisms can be used to foster the most effective approaches. The continuing creation of such innovative partnerships will allow NCATS to leverage the collective expertise of multiple sectors to identify other market-based solutions and to fund the most meritorious peer-reviewed proposals to speed the commercialization to detect, treat, and prevent disease.

9) Please identify when the trans-NIH workshop with industry, academia, PTO, FDA, and others will be scheduled to consider how existing NIH mechanisms can be used to encourage models around the country to speed commercialization of therapies through a market-based approach as described in the FY 12 Statement of Managers. Plus, identify how the request will be advertised for participants.

Answer: The National Center for Advancing Translational Science (NCATS) is focusing on the analysis and development of models to facilitate the commercialization of federally funded basic and applied research discoveries and on research that will help "de-risk" the drug development process. A number of stakeholder outreach activities are underway to identify and develop models of innovative public-private sector collaborations to speed therapeutic development. For example, meetings held with industry, academia, and the Food and Drug Administration in the last year culminated in the establishment of a collaboration to speed the commercialization of therapies by finding new uses for existing molecules and drugs. In early May 2012, NIH announced a new collaborative program between the biomedical research community and pharmaceutical company partners to explore new uses for discontinued proprietary drug candidates across a broad range of human diseases. A key element of the program incorporates innovative template agreements designed to streamline the legal and administrative process for participation by multiple organizations. These template agreements reduce time, cost, and effort, as well as allow greater participation than traditional partnerships. The program is also designed to leverage the expertise and innovative ideas of the entire U.S. biomedical research community. The discoveries that emerge from this program could be commercialized by the participating companies or third-party companies around the country.

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10) The FY 12 clearly intended a base increase for the IDeA program with have the increase going toward multi-year COBRE awards and the other half towards multi-year IDeA Clinical Trial and Translational Program awards. Please provide a spend plan for the $276,480,000 provided for IDeA that highlights the directed increase focus areas as compared to FY 2011. Identify, at the NIH Budget request level for FY 2013 how many of each IDeA program activities would be halted or reduced, as compared to the congressionally enacted FY 12 level for IDeA.

Answer: The following spending plan highlights the increases in the FY 2012 bill language compared to FY 2011 (dollars in thousands), after reduction for the rescission:

	FY2011		FY2012 COMMITMENTS		Plus FY2012 COMPETING		Plus FY2012 COMPETING FROM CONGRESSIONAL INCREASE		Totals FY2012 APPROPRIATION	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount	Number	Amount
INBRE	25	$ 75,930	25	$ 77,547					25	$ 77,547
COBRE	78	$ 150,550	60	$ 110,910	14	$ 19,000	10	$ 20,000	84	$ 149,910
CTR *					1	$ 20,000	1	$ 20,000	2	$ 40,000
COFUNDING **					10	$ 2,600	23	$ 5,900	33	$ 8,500
TOTAL	103	$ 226,480	85	$ 188,457	25	$ 41,600	34	$ 45,900	144	$ 275,957

* Funds provided for the CTR grants in FY2012 will support the grants for 5 years.
** Note the other IC will get the grant count when final reporting is complete.

In total, the FY 2013 Budget proposes to reduce COBRE and INBRE IDeA programs supported in FY 2012 by approximately -4 percent. Within the total proposed FY 2013 budget request for

IDeA, NIH would utilize funds made available from grant turnover to support new or renewed COBREs and to sustain the FY 2012 co-funding commitment. No new IDeA Clinical and Translational Research Center (CTR) commitments would be made in FY 2013, nor will any additional co-funding be initiated.

11) Please provide a status report and timeline on when NIH expects to schedule the briefing with the Committees on the third party collections 3-year pilot included in the FY 12 enacted bill and report.

Answer: By the end of April 2012, the following preparatory steps had been taken:

- Solicited input from NIH. Convened NIH oversight groups to review a proposed timeline and solicit input about candidate areas for a pilot. Groups consulted with include:
  - NIH Advisory Board for Clinical Research (ABCR)
  - Clinical Center Governing Board (CCGB)
  - NIH Medical Executive Committee (MEC)
  - Patient Advisory Group (PAG)
- Identified potential pilot areas. As a result of the input gathered from NIH stakeholders, several areas have been identified for further exploration.
- Issued Request for Proposals (RFP). Developed a Statement of Work for consultant support to engage with experts in the field of third party reimbursement to develop a plan of action for a third party reimbursement pilot. This effort will include the determination of a final pilot recommendation based on identification of high level requirements for each option; input from experts in academic medical centers, insurance companies, federal medical facilities and CMS.

Upcoming activities:

- Responses to the RFP, due May 3, 2012, will be analyzed for pilot planning effort.
  - Work to design the pilot will commence June 2012.
- Final pilot recommendation will be presented to Congress, as the Committees on Appropriations expect to be briefed on the proposed subject area and scope of the pilot before it is finalized.

12) Please provide an update with a detailed timeline on the status of the NIH-wide Clinical Trials review that is directed in the Statement of Mangers.

Answer: The Office of the Director is in the process of developing a survey instrument that will be used to gather information from the Institutes and Centers (ICs). Questions on the survey are designed to respond to the Statement of Managers directive to conduct a trans-NIH review of the applicability of the recommendations that the Institute of Medicine made on the National Cancer Institute Cooperative Group Program ("A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program"). The report will include a discussion of how the IC's prioritize, innovate, and enhance the efficiency of the conduct of clinical trials. As requested, and as appropriate, based on the findings and analysis, the report will also include proposed policy changes to enhance the monitoring of clinical trial activity. The ICs will be surveyed in early spring and will have one month to complete the survey questions. Data analysis will be underway in early summer. Once data analysis is completed (mid-July), a draft report will be developed. The draft report will be reviewed by the ICs for accuracy and

completeness. The final version of the report is expected to be submitted to Congress by September 30, 2012.

13) The FY 12 Statement of the Managers noted "In recent years, extramural research has accounted for nearly 90 percent of NIH's budget. The conferees strongly urge NIH to maintain at least that level in fiscal year 2012. NIH should also establish safeguards to ensure the percentage of funds used to support basic research across NIH is maintained." The numbers provided by NIH indicate the amount of expenditures on Basic Science in FY 2012 is estimate is $16.045 billion or 52% and the FY 2013 level decreases to $15.987 billion or 51.8%. However, in your testimony to the Committee, you noted a higher percentage.

We appreciate the importance of basic and translational science. However, we must ensure an increased focus on translational research does not squeeze out NIH's primary mission -- that of basic science. As I stated earlier, NIH's data shows an expected drop to nearly 51 percent or about $1 billion off the mark.

It would be regrettable to wake up in the future without a stable full of science available for translation because we took our eye off the ball of basic science.

Please describe how NIH has established a trans NIH process to comply with the letter and spirit of the guidance provided by Congress in the Statement of Mangers to ensure basic science is not negatively impacted, especially in light of the new authority we provided through NCATS?

Plus, how will NIH and each IC ensure the focus on basic science is not lost during execution of spending the resources provided to NIH?

Please explain how NIH does or will conduct a trans-NIH mid-year reviews on spending priorities areas like basic science and extramural research allocations to ensure the enacted policy is implemented appropriately.

Answer. NIH's commitment to improve our understanding of human biology and expand our knowledge of the fundamental underpinnings of health and disease is abiding and will persist in the future. Investments in basic biomedical and behavioral research make it possible to characterize more accurately the causes of disease onset and progression, design preventive interventions, develop better diagnostic tests, and discover new treatments and cures. From the incremental advances in our understanding of a given disease to the groundbreaking discoveries that revolutionize our approaches for treating or preventing it, investments in basic research have yielded inestimable rewards and benefits to public health. Fostering a broad basic research portfolio is a critical component of fulfilling the NIH mission. Continued support for basic research is essential for the agency to be successful in advancing the translation of basic discoveries into new diagnostics and treatments. Moreover, breakthroughs in our understanding of scientific targets and pathways also have secondary effects that stimulate new avenues for scientific inquiry.

Each NIH Institute and Center (IC) relies on its own process for ensuring that resources are allocated in accordance with appropriations and other relevant laws, Administration priorities, scientific opportunity, public health needs, and IC strategic goals. The ICs account for many factors during their annual allocation of budgetary resources, including supporting a project mix that balances their basic, translational and clinical research portfolios as well as responding to public health needs and exploiting scientific opportunities. Some ICs may also have

Congressionally-mandated directives that must be addressed. Spending plans generated by each IC address these factors, and they are adjusted throughout the year based on the portfolio of grants and contracts funded at any particular point. It is important to note that these spending plans must remain flexible to account for scientific opportunity and a certain level of unpredictability in the outcome of any particular round of application receipt and review. For example, because of the importance placed upon investigator-initiated research, it is not possible to predict from one round of funding to the next whether a predominance of unsolicited applications in basic vs. translational research will be submitted.

As part of the annual budget formulation process, the Office of the Budget, NIH (OB), calculates overall percentages for NIH's investment in basic and applied research before finalization of the President's Budget request. The OB compilation involves consolidating data submitted and individually coded by each IC. The basic percentage has been remarkably constant for over five years.

National Institutes of Health
Distribution of Actual Obligations or Budget Authority to
Basic vs. Applied Research*

	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Enacted	FY 2013 PB
Basic	51.6%	53.6%	53.8%	53.6%	53.4%
Applied	45.4%	46.4%	46.2%	46.4%	46.6%

Note: */ Percentages exclude amounts allocated for R&D facilities and training.

Let me also explain why two different percentage estimates exist for the share of the overall NIH FY 2013 budget devoted to basic research. The difference in the two figures, roughly 2 percent, is due to a difference in calculation methods. In my testimony and in the Overview section of our FY 2013 budget request, I reported that NIH funding for basic research is slightly over half (54 percent) of our budget and that the balance between the two types of research has remained fairly constant over the past decade. The 51.8 percent figure was generated by the NIH FY 2013 estimate details that are entered into the Federal government-wide budget data entry system (MAX) administered by the Office of Management & Budget. The 51.8 percent estimate is derived when the FY 2013 basic science estimate is divided by the total NIH budget request —where the NIH total includes amounts not assigned to either basic or applied science. Using this formula, the estimated share of NIH research devoted to basic research changes by -0.2 percent from 52.0 percent in FY 2012 to 51.8 percent in FY 2013. The 54 percent figure uses a different denominator for share calculation that excludes amounts for activities that do not fit within either primary category, such as Training, from the total. Using this formula, the estimated ratio of NIH research devoted to basic research as compared to applied research changes by -0.2 percent, from 53.6 percent to 53.4 percent between FY 2012 and FY 2013. In both cases, the difference is accounted for by a shift of $60 million from basic to applied research between FY 2012 and FY 2013, which in the context of the overall NIH budget is likely

due, not to any one factor, but to slight variations in allocations made by ICs given projected funding levels of many different budgetary mechanisms.

14) I understand, on occasion, once NCATS efforts have developed a new process or technique to speed the drug development process, it will require testing in a phase I or II clinical trial to evaluate the new method. The result will not only test the new process, but also potentially reduce the risk of the compound tested or as I believe you call it "de-risking" the compound.

In the Statement of Managers, Congress asked NIH to ensure the selection of projects contemplate the future market acceptance as one component of the criteria in selecting the compound used for the test. In other words, NIH should ensure that in addition to the scientific aspects of compound selection, positive net present value is part of the selection criteria.

Please describe the criteria NIH will use to select the new projects described in the budget request, like the efforts to examine how drug targets will have the desired therapeutic effect and ways to repurpose.

Please explain what weight a positive net present value will be allocated in the process to select the compounds to evaluate or "de-risked" a new process?

Please identify the specific criteria factors and weight used to select the proposed 2013 projects with DARPA to develop microchips of human cells and tissue to determine if it might provide a method to test toxicity of compounds in humans? Plus, what assurance can be provided related to this project that the NIH funds are supplanting an existing funding stream for this project?

Answer: NIH notes the Committee's suggestion that the selection of Center projects should consider future market acceptance as one of the components in evaluation process, but NCATS will use a number of criteria to select new programs. Chief among these criteria will be the potential for the program to address a critical barrier or bottleneck in the drug and therapeutics development pipeline. NCATS will identify these barriers and bottlenecks in consultation with pharmaceutical companies, biotechnology companies, nonprofits, patient groups, and academic medical centers.

The value of NIH's investment in new resources and tools will be measured in the new knowledge generated and the utility of these resources and tools to the drug and therapeutics development process.

Projects under the DARPA-NIH collaboration entitled "Integrated Microphysiological Systems for Drug Efficacy and Toxicity Testing in Human Health and Disease" will be selected based on project significance, suitability of the investigator, innovation and soundness of approach.

NIH has an MOU in place with DARPA that allows sharing of information and partnering to ensure that the science supported by the two agencies is complementary and not duplicative.

15) Related to NCATS, identify specific projects you believe are ripe for NIH to leverage basic science to improve how the pharmaceutical industry can accelerate moving discoveries into treatments. Plus, provide a sense of how long it would take for this effort, I assume these will all take years to complete.

Answer: There are many areas in which NIH can leverage research to accelerate industry therapeutic development efforts. For example:

1) Improving methods for assessing and predicting toxicological effects of drugs in development. Animal toxicology is a major cause of drug development failure by virtue of being both extremely costly and relatively unchanged over the last 50 years. Replacing animal testing with cell and screening-based methods entirely is an exceedingly complex endeavor which will require at a minimum ten years to establish scientifically and likely a further ten years for acceptance by regulatory agencies. Fortunately, technologies and predictive data to replace or improve some tests can and will happen within the next five years.

2) Develop new methods for creating novel chemical diversity. The types of chemical compounds used to screen for potential therapeutic effects against molecular targets has remained relatively static. New methods are needed to develop a more diverse group of small molecules, biologics, and other types of biological molecules. Novel chemistry technologies can add unique dimensions to drug discovery paradigms with the potential for advancing nontraditional clinical tools and cutting-edge reagents for studying cellular processes. Timing would be approximately ten years.

16) The law specifically states NCATS must operate in ways that do not create duplication, redundancy, and competition with industry activities. In addition, the Statement of the Managers accompanying the conference agreement stated that in all the NCATS efforts, the conferees expect NCATS will complement, not compete with, the efforts of the private sector.

The request identifies activities for the Cures Acceleration Network, a Defense Advanced Research Projects Agency (DARPA) activity, to develop microchips of human cells and tissue, and a list other activities related to drug targets and ways to repurpose drugs for new indications.

I appreciate NCATS is creating its Advisory Board. However, neither the written testimony or budget request clearly identifies how NIH or NCATS will ensure all projects and activities will not create duplication, redundancy, and competition with industry activities.

Dr. Insel, please describe exactly what type of governance process is being established to ensure this aspect of the law is complied with and exactly when and how industry will be able to comment on the proposed process. I assume no new projects or partnership can really move forward until this is accomplished. It would seem all potential projects need to be vetted with industry well in advance as it is unlikely NIH will know what industry has planned or is doing.

Again, Dr. Insel please describes how NCATS will ensure its activities compliment and do not create duplication, redundancy, and competition with industry activities?

Plus, when do you expect the federal notice and comments regulations will be published that will identify the process NIH expects to use to communicate with industry in an open

and transparent manner? How long of a comment period does NIH envision for the public comment on these regulations? Also, highlight how input from industry will be collected and evaluated?

Answer: The governance of NCATS will be the same as for all of the other Institutes and Centers at NIH, in that there will be an NCATS Advisory Council which will provide input and advice on all proposed initiatives, in addition to providing the second level review of applications. NCATS will also have the CAN Review Board, which will have similar membership as the Advisory Council, to provide advice into the activities supported through CAN. These groups will have members with expertise in biopharmaceutical development and discovery and delivery of medical products, as well as representatives from venture capital and private equity organizations. Advice from these members with expertise across industry will help ensure that NCATS does not overlap with activities of the pharmaceutical industry. The meetings of these groups, which will occur at least three times a year, will be open to the public, which will allow opportunities for public input to proposed initiatives.

Another effective way to ensure that NCATS activities do not duplicate or compete with industry activities is to involve industry, where appropriate, as NCATS develops new initiatives and programs. For example, prior to the establishment of NCATS, NIH held a Roundtable in April 2011 that brought together senior leaders and experts from the pharmaceutical industry, government, academia, and the nonprofit sector to explore opportunities to foster new partnerships that could facilitate drug rescuing and repurposing. This meeting led to the development a new initiative to discover novel therapeutic uses for existing molecules, where NCATS will collaborate with pharmaceutical companies to match academic researchers with existing molecules to explore how they might be used to treat disease. By making some of industry's existing molecules available to a broad spectrum of academic researchers, NCATS complements, and does not duplicate, work already performed by industry. In addition, there will be a Request for Information that specifically asks for input on this novel public private partnership and provides an opportunity for individuals and organizations to express their views and concerns, if any.

NCATS is working closely with industry through inclusion of private sector members on our council and through direct and ongoing consultation. NCATS' staff interacts regularly with PhRMA and BIO as well as individual companies. Moreover, we are developing systematic methods to seek their input on what barriers to drug development might be amenable to NCATS research. NCATS' current communication strategy is effective and timely. We have received no indication from industry that a notice and comment rule making process is their preferred method of communicating and interacting with the NIH.

17) Stewardship and oversight are critical elements of the Appropriations Committee to ensure precious tax payer funds are used properly.

The recent $1.4 billion Anti-deficiency Act (ADA) violation submitted to Congress last July by the Department of Health and Human Services (HHS) identified that out of a sample of 176 contracts, 47 or slightly less than 30 percent, had at least one ADA violation. I note this again as 21 of the contracts were from various components of the National Institutes of Health (NIH). We must ensure accountability and appropriate follow-through occurs.

The HHS Office of Inspector General (IG) issued at least 16 reports on the NIH violations. Dr. Collins, if you have not done so, please review my recent opening statement to the Secretary. In addition, I request a report that details the implementation status and expected completion date for each recommendation made by these IG reports to any NIH component.

Answer: In response to the Anti-Deficiency Act violations you noted in your opening statement at the March 6 Subcommittee hearing on the HHS Budget, the National Institutes of Health (NIH) has taken corrective action across the agency including modifying policies and procedures to address the long-standing problem which created the resulting violations. NIH has promoted the use of the multi-year contracting mechanism, codified at 41 U.S.C. 254c, which authorizes agencies to structure contracts using flexible funding methods and developed an instructor-led course on multi-year contracting tailored to the NIH environment to train and familiarize staff with how to award and administer a multi-year contract. NIH also established classroom-based training on appropriation law to enhance the available training. NIH will continue to deliver this class this fiscal year and next. NIH continuously shares successful appropriations-related business practices, and its Office of Acquisition and Logistics Management provides technical assistance across NIH to ensure full compliance with appropriations law and HHS policy. Additionally, NIH conducts acquisition management and internal control reviews to validate full compliance with appropriations law and HHS policy. NIH, in cooperation with the Department of Health and Human Services, continues to implement a corrective action plan that addresses these matters, continues to improve and enhance sound financial management systems and processes, and remains committed to the proper and lawful funding of contracts.

18) I recently received a document which is titled "NIH Common Fund's Health Economic Program makes First Awards". It notes NIH is undertaking economic research, particularly as it relates to the implementation of health care reform.

In fact, one of the categories is on the "Market for Long-Term Care Insurance", which funds studies related to the now halted Community Living Assistance Services and Supports (CLASS) program. Another category of research is titled "Integrating Comparative Effectiveness Research Finding into Care Delivery through Economic Incentives." This category includes a grant to influence doctors to adoption cost-saving practices and examine doctor's influence on the costs of care in the Medicare population.

The NIH's primary mission is basic biomedical research... not economics, we fund other agencies to conduct economic research. Given concerns raised about the number of quality basic biomedical research applications NIH cannot fund....why spend these precious resources on ObamaCare economics research.

Specifically, what role do you expect these studies, and other NIH studies like these, will play on the rationing of care under ObamaCare. Also , explain why and how much NIH has spent on health economics research from the common fund and other sources in FY 2011, estimated for FY 2012 and FY 2013? Finally, please explain why NIH has funded studies for a program that even the Obama Administration has halted (the CLASS Act long term care program).

Answer: NIH is working with AHRQ and other agencies to collaborate on this critical issue to ensure that it does not conflict with their efforts and missions. NIH's mission is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and

disability." We initiated this Common Fund program in Health Economics as a way to measure the success of the translation of the benefits of our research into enhanced health of the U.S. population.

None of the grants under the Health Economics program of the Common Fund, nor any grants made by individual institutes and centers, concern rationing of medical care. NIH does not fund policy research, it funds basic and applied research, biomedical and behavioral, that can be used to inform clinical practice and, as a result, health policy.

The Request for Applications on "Integrating Comparative Effectiveness Research Finding into Care Delivery through Economic Incentives" (RFA RM-11-011) sought research to determine the ways results from CER can be incorporated by providers, consumers, and payers, to make changes in clinical practice to improve the quality of care for patients and restrain growth in health care costs. The three grants funded under this announcement include a study of the role of provider networks on the use of evidence-based practices and costs of care in the Medicare population (Bhattacharya; 1-R21-AG041112-01), the effects of warnings and incentives designed to reduce the use of the drug Epoetin to treat anemia in end stage renal disease (Swaminathan; 1-R21-DK09548501), and whether personalized risk and benefit information along with economic incentives will result in more diabetic patients having routine cholesterol testing and remaining on treatment regimens with statins (Wong; 1-R21-AG04232601). New research such as this is needed to understand if such incentives work to improve health.

Health Economics Portfolio

There is no specific program in health economics beyond the Common Fund program. Most institutes have as a part of their portfolio, research in disease prevention, long-term care for chronic diseases, behavioral sciences relevant to health, or community-level health interventions, grants that use the methods and models of health economics.

Below are the specific amounts awarded or budgeted for the Common Fund Health Economics program.

	FY11 # Awards	FY11 Actual	FY12 Estimate	FY13 Estimate
Common Fund Health Economics (CFHE) Existing Awards	21	$5,401,418	$4,725,606	$1,238,775
Budget for Additional CFHE Awards	0	$0	$3,600,000	$11,300,000
Budget for CFHE Contract	0	$0	$1,500,000	$450,000
Total	21	$5,401,418	$9,825,606	$12,988,775

CLASS ACT and Long-Term Care

One Request for Applications under the Health Economics program of the Common Fund (RFA-RM-11-002) solicited applications for "research on the economics of long-term care, including

topics related to the CLASS program, private and public long-term care insurance, and related topics." Long-term care is among the biggest uninsured financial risks facing older workers and the elderly, and the aging of the US population will greatly increase the number of persons facing potentially severe financial hardship in coming years.

There are five grants on long-term care in the Common Fund program; they deal more generally with the market for long-term care insurance rather than with specific features unique to the CLASS program. The research is relevant to the supply of and demand for long-term care insurance and is not diminished by the suspension of CLASS.

One grant (Webb, 1R01AG041105-01) is to develop an economic model for how households make decisions on saving and long-term care insurance. One of the four specific aims of this analysis proposed to use the model to analyze the likely response to the CLASS Act long-term care insurance program. However, since CLASS has been suspended, this aim is being refocused to conduct a generic analysis of responses to insurance provisions.

19) The future of biomedical research depends on a strong cadre of bright, young scientists. The data in the proposed President's request reduces the number of training awards for the second year in a row. It seems to run counter to that premise of support stated by you. What would be the direct impact of reduction of training stipends as proposed in the budget request, if enacted? What is the number of training slots required to ensure an appropriate level pipeline of young investigators is maintained.

Answer. NIH continues to support the development of a vibrant, skilled scientific workforce by attracting and retaining the most talented individuals. The formal NIH training programs have been highly successful in producing a cadre of individuals that are more successful in getting NIH research grant awards and publishing papers, and those papers are more highly cited that those from graduate students who completed their training at the same time in similar fields. In spite of the well documented success of our training programs, the NIH continues to carefully analyze the research workforce and training needs. NIH has recently appointed a high-level taskforce to examine the current structure of careers in biomedicine and report back to the Director's Advisory Committee. The task force is expected to report findings to the Director's Advisory Committee by June 15, and these results will inform future budget requests.

The 2013 President's budget requests a 2 percent across the board stipend increase for research training in order to continue a long-term strategy to bring stipends into line with salaries that could be earned in comparable positions. This is directly related to the need to attract the best and brightest young scientists into health-related research. The requested 0.4 percent reduction in the training budget will result in 309 fewer positions or about 1.8 percent of all training positions. Considering that more graduate and postdoctoral students are supported by NIH research grants than through formal training programs, it is expected that the proposed reduction in the training budget will decrease the overall number of training positions by less than 0.5 percent. This small decrease is not expected to affect the pipeline of young investigators in any detectable way.

20) Over the years you have probably encountered an issue thought to be settled only to see it overturned by new research findings. That appears to be the case with the issue of

sodium and health. Decades of NIH supported neuroscience research has identified specific, integrated neural networks interfaced with peripheral hormone signals. These neural networks regulate sodium intake within a narrow range. We have provided a copy of a recent review of this body of NIH supported research. This neuroscience research predicted recent, disturbing findings from clinical studies. These human studies indicate that modest reductions in sodium intake are associated with stimulation of hormones systems associated with increased CVD mortality. Further they appear to document that a patient population specifically targeted by our current sodium policy, congestive heart failure, appears to be at greatest risk.

In an effort to assure that the country and its citizens benefit from both past and current NIH supported research related to sodium and health, please review the neuroscience of sodium appetite and provide an analysis of the two clinical studies that have identified this increase risk of death with modest sodium reduction and report back to the subcommittee. We would hasten to add that there are a number of additional reports published in the past 2-3 years that you would find consistent with science in these three publications.

- **Graudal N, Hubeck-Graudal T, Jurgens G. Effects of Low-Sodium Diet vs. High-Sodium Diet. Am J Hypertension November 9, 2011**
- **O'Donnell MJ, Yusef S, et. al. Urinary Sodium and Potassium Excretion and Risk of Cardiovascular Events. JAMA November 13, 2011**



Sodium Appetite Exp Physiol 0208.pdf

Answer: Based on a review of the literature, we conclude that there is insufficient evidence to state that reducing sodium to current recommended levels is associated with major adverse consequences. (Recommendations are that Americans 2 years of age or older reduce dietary sodium intake to less than 2,300 mg/day, and that intake be further reduced to 1,500 mg/day for people who are 50 years of age or older, are African American, or have hypertension, diabetes, or chronic kidney disease.) Our reasons are as follows:

1) Sodium is an essential nutrient that is important in regulating plasma volume. The balance of sodium and other electrolytes is closely regulated in the body through several pathways, including the renin–angiotension–aldosterone axis. Geerling et al. (2008) reviewed these pathways and described neurohormonal mechanisms for sodium appetite based on animal models. As the authors pointed out, "more rigorous data are needed regarding the regulation of sodium appetite in humans" and "sodium appetite may not be as strong a behavioral drive in humans." Given the lack of research in humans, it is unclear that these physiological mechanisms drive humans to consume salt above recommended levels.

2) In their meta-analysis of 167 sodium-reduction trials, Graudal et al. (2011) concluded that sodium reduction resulted in some decrease in systolic blood pressure in people with normal blood pressure and a greater decrease in people with hypertension, along with an increase in plasma renin, plasma aldosterone, plasma adrenaline and noradrenaline, blood cholesterol, and triglyceride. Unfortunately, many of the trials were not blinded and did not use standard intent-to-treat analyses. More important, most of the trials were of very short

duration, which probably contributed to the acute metabolic and hormonal effects noted. Indeed, when analyses were limited to trials 4 weeks in duration or longer, changes in blood cholesterol, triglycerides, noradrenaline, and adrenaline were no longer statistically significant. Renin and aldosterone are known to rise in response to reduced sodium intake as part of a system that regulates the balance of sodium and other electrolytes. However, increases in renin attenuate with longer duration of sodium restriction. An additional serious concern is that Graudal et al. did not specify the level of sodium restriction in the trials that found increases in renin and aldosterone. Thus, it is impossible to evaluate whether the sodium restrictions were within the range of recommended dietary sodium intake for the U.S. population.

3) Even if sodium restrictions within the range of recommended intake did lead to increases in renin and aldosterone, the evidence does not suggest adverse effects due to these increases. Evidence from observational studies has not found a consistent association between plasma renin levels and cardiovascular disease (CVD) mortality (Alderman et al., 1991; Gonzalez et al., 2011; Meade et al., 1993). Aldosterone likely is not a CVD risk factor but, rather, a reflection of sodium and volume status (Rossi et al., 2005).

4) O'Donnell et al. (2011) examined the relationship of dietary sodium to CVD outcomes in patients enrolled in two drug trials. The data indicated that both high and low sodium intake were associated with increased risk of CVD events in a J-shaped relationship. This study has been widely criticized in published reviews and letters (Whelton, 2011; Mann, 2012; He and MacGregor, 2012). Its main limitation was the method for estimating dietary sodium intake for individuals. Whereas measurement of 24-hour urinary sodium excretion over multiple days is considered optimal, the authors used a first morning void to estimate urinary sodium excretion over a 24-hour period. The use of a partial urine sample is generally considered inaccurate because sodium excretion varies greatly throughout the day and can be affected by low sodium intake, the use of loop diuretics, age, and hypertension status. Given that these patients were older and had CVD (including hypertension) or were at high risk of developing it, the use of a partial urine sample is particularly unacceptable. In addition, many of the patients were ill and may have changed their dietary habits, including reducing sodium intake, before taking part in the study. Thus, those with lower sodium intake may have already had CVD.

5) Evidence of increased mortality or morbidity from sodium-reduction trials is lacking. In five of six trials, reduced sodium intake was associated with a significant reduction in CVD morbidity and mortality; the only trial finding an increase in CVD risk was one in heart failure patients (Taylor et al., 2011). The American Heart Association and the American College of Cardiology recommend diuretics and salt restriction as part of care for patients with heart failure (Hunt, 2005), acknowledging that this is based mainly on consensus opinion of experts, case studies, or standard-of-care. The NHLBI recognizes the need for more data on the effects of sodium restriction in patients with heart failure.

6) The expert panel convened by the Institute of Medicine in 2004 to set dietary reference intake levels for sodium reviewed the evidence on potential adverse effects of sodium reduction. It noted that plasma renin rises in response to a reduction in sodium, blood volume, or blood pressure. It also noted that plasma renin commonly rises in response to blood-pressure–lowering medications, including thiazide diuretics, which are often used to

treat hypertension. Despite this rise, diuretic therapy has been shown to prevent stroke and coronary heart disease (Psaty et al., 2003). With respect to concerns that low sodium intake may be associated with adverse effects, the panel concluded that at 1,500 mg/day, "the preponderance of evidence does not support this contention."

In sum, given the demonstrated benefits of sodium reductions to 1,500-2,300 mg/day with regard to blood pressure and the uncertainties about whether expected rises in renin and aldosterone in response to such reductions are clinically meaningful, the reduction of dietary sodium intake to recommended levels is warranted.

References:

Alderman MH et al. Association of the renin-sodium profile with the risk of myocardial infarction in patients with hypertension. N Engl J Med. 1991.

Geerling JC, Loewy AD Central regulation of sodium appetite. Exp Physiol. 2008.

Gonzalez MC et. al. Enduring direct association of baseline plasma renin activity with all-cause and cardiovascular mortality in hypertensive patients. Am J Hypertens. 2011.

Graudal N, et al. Effects of Low-Sodium Diet vs. High-Sodium Diet. Am J Hypertension. 2011.

He FJ, MacGregor GA. Salt and cardiovascular risk. Nat. Rev. Nephrol. 2012.

Hunt SA et. al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology /American Heart Association Task Force on Practice Guidelines. Circulation 2005.

Institute of Medicine (U.S.). Panel on Dietary Reference Intakes for Electrolytes and Water. Dietary reference intakes for water, potassium, sodium, chloride, and sulfate. National Academy of Sciences, 2005.

Mann S. Urinary Sodium Excretion and Cardiovascular Events. JAMA 2012.

Meade TW et al. Plasma renin activity and ischemic heart disease.N Engl J Med. 1993.

O'Donnell MJ, Yusef S, et. al. Urinary Sodium and Potassium Excretion and Risk of Cardiovascular Events. JAMA 2011.

Psaty BM et al. Health outcomes associated with various antihypertensive therapies used as first-line agents: a network meta-analysis. JAMA 2003.

Rossi G et al. Aldosterone as a cardiovascular risk factor. Trends Endocrinol Metab. 2005.

Taylor RS et al. Reduced dietary salt for the prevention of cardiovascular disease. Am J Hypertens. 2011.

Whelton PK. Urinary Sodium and Cardiovascular Disease Risk. JAMA 2011.

21) Radiation oncology and diagnostic radiology are often confused and comingled in the NIH tracking systems. As you know, diagnostic radiology uses a low-dose of radiation to view inside the body, while radiation oncology uses targeted high doses of radiation to kill cancerous tumors. I would like to request that NIH provide the Committee with a detailed report on the projects funding in FY2010, FY2011 and FY2012 for all projects specifically involving radiation oncology by all Institutes and Centers and NIH in total.

Answer: Radiation oncology is the medical use of ionizing radiation, generally as part of cancer treatment to control or kill malignant cells. Grants, research and development (R&D) contracts, and intramural research projects are provided for FY 2010 and FY 2011. Whereas, only a partial list of research grants is available for FY 2012 because NIH funds research throughout the fiscal year.

An extensive list of projects was collected in response to this question. Each project list was reviewed by the appropriate IC and validated for accuracy. Due to the volume of grants, we have summarized the project lists below and the master list of projects, supporting the summary table, can be found at http://officeofbudget.od.nih.gov/pdfs/FY12/NEWConsolidate_summary_final_5-15-2012.pdf. The summary results are furnished below by IC and FY.

THE NATIONAL INSTITUTES OF HEALTH (NIH)

Radiation Oncology Projects

	FY 2010 ACTUAL		FY 2011 ACTUAL		FY 2012 YTD*	
IC	**# of Projects**	**Award Amount**	**# of Projects**	**Award Amount**	**# of Projects**	**Award Amount**
NCI	473	$207,771,256	487	$238,316,315	130	$61,778,215
NCRR	29	$5,865,427	15	$30,543,717		
NHLBI	5	$1,848,251	7	$1,643,095	2	$376,956
NIAID	3	$1,085,446	3	$1,016,175		
NIBIB	5	$1,699,580	6	$696,883		
NICHD	2	$1,078,343	2	$158,884		
NIDA			1	$325,205		
NIDCD	1	$428,419	2	$793,952	1	$40,511
NIDCR	6	$1,545,500	4	$1,073,142		
NIDDK	1	$121,936				
NIEHS	1	$310,326	1	$236,199	1	$323,414
NIMH	1	$41,000	1	$543,088		
NINDS	9	$2,900,018	12	$10,707,277	5	$4,952,862
NINR	4	$1,311,553	3	$4,417,724		
NLM	1	$453,884				
OD	1	$2,655,000				
Total	**542**	**$229,115,939**	**544**	**$290,471,656**	**139**	**$67,471,958**

*Year-to-Date includes all grants through the end of March.

22) There appears to be growing research interest in the issue of mitochondrial disease and dysfunction. The NIH has undertaken some efforts over the past few years to promote research in this area. Among other activities, variations in mitochondrial function were a focus area for the Transformative Research Awards (T-R01s) that NIH announced a few years ago and NIH recently held a symposium on Translational Research in Primary Mitochondrial Diseases that involved the participation of numerous institutes and the invaluable leadership of the Office of Rare Diseases. Mitochondrial research is a true example of a cross-cutting area of research -- with well over a dozen NIH institutes involved in various aspects of this subject.

We understand there is a growing body of evidence relating mitochondrial dysfunction to a host of major illnesses and conditions -- including Parkinson's, ALS, autism, diabetes and others. For example, researchers at Mayo recently reported on their research that led them to conclude that mitochondrial dysfunction is "an underlying event in Alzheimer's disease progression". Can you comment on this growing body of evidence and what NIH is doing to ensure that this evidence is being shared across disciplines, disease research areas and institutes?

Do you anticipate mitochondrial research continuing to be a focus area for common fund-related research? Can you provide a summary of common fund-supported research in this area?

Answer: Although severity varies, by and large mitochondrial diseases are progressive and crippling disorders. The North American Mitochondrial Disease Consortium (NAMDC) and the United Mitochondrial Diseases Foundation (UMDF) are working with NIH to address these challenges. NAMDC, part of the Rare Disease Clinical Research Network (RDCRN), was developed by the Office of Rare Diseases Research of the National Center for Advancing Translational Sciences (NCATS). It has begun work on an integrated, international patient registry for 28 mitochondrial diseases at 10 clinical centers across the United States and Canada in collaboration with the UMDF. The consortium conducts integrated, multi-project, and multi-institution research in rare diseases, while also training the next generation of rare disease researchers.

A recent scientific conference was an important first step for continuing the dialogue among representatives of the mitochondrial disease research and patient communities. Researchers, NIH program representatives and intramural scientists, and patient advocates met on March 8-9, 2012 to discuss barriers and opportunities for primary mitochondrial diseases research. The NIH investment in mitochondrial disease is broad and comprehensive. There appears to be an opportunity to conduct more scientific meetings to encourage cross-information and to implement recommendations developed jointly by NIH ICs and the UMDF, especially for primary mitochondrial diseases.

Although Common Fund (CF) programs do not focus specifically on mitochondrial diseases, the CF issued 20 awards relevant to the topic in FY 2011. Most of these awards were funded as part of the High Risk/High Reward Program, which includes the Pioneer, New Innovator, Transformative Research Awards, and Early Independence Award initiatives.

Questions for the Record
From Congressman Harold Rogers

Question 1: In the FY12 Conference Report, the committee asked that NIH ensure that part of the criteria for accepted projects be some measure of how the products produced will be accepted by the market. In doing so, the process would ensure that these products will have a positive impact on the market once they are introduced.

A. Please describe the criteria used to select the new projects described in your budget request, such as the efforts to examine how drug targets will have the desired therapeutic effect or possible repurposing.

B. In the selection process, what weight is given to market acceptability?

Answer: Applicants are asked to indicate the disease, clinical population, and public health need that will be addressed by the proposed new use of the agent as well as the global burden of disease, which patients will benefit, how they will benefit, how use of the agent will be superior to current therapy options and potential for impact on public health. In addition, applicants and reviewers are asked about future development of molecules. Market acceptability is an embedded part of several selection criteria.

Question 2: I understand that positive strides have been made in the basic research in understanding the genetic causes and effects of Spinal and bulbar muscular atrophy, or Kennedy's Disease. I also understand that there have been successful tests in mice relating to inhibiting this disease and clinical trials are continuing on Kennedy's Disease patients.

A. What is the timeframe anticipated before human trials for possible treatments are conducted?

B. What is the anticipated timeframe before a cure for Kennedy's Disease could be available?

C. Do advances in the basic research for Kennedy's Disease translate into substantial breakthroughs in research into other genetic neurological diseases?

Answer: Although basic research has driven encouraging progress, predicting when a cure will be available for Kennedy's disease (also called SBMA) would not be prudent because of the enormous challenges of developing a treatment that slows the underlying disease process for any neurological disease. The discovery of the genetic error that causes SBMA implicated a defect in the androgen receptor, a protein that enables cells to respond to testosterone-related hormones. Exactly how that gene change leads to the progressively disabling, and even fatal, muscle weakness of the disease was not clear. However, the gene discovery led to rational therapeutic strategies based on androgen biology, and to animal models that mimic key aspects of the disease, which enable researchers to study the disease process and to test interventions at multiple steps. To date, three randomized, placebo-controlled human clinical trials of candidate therapies have been reported for SBMA, but none found a significant benefit in slowing the disease. The trials included one reported last year from the NIH Clinical Center

which did provide information on the disease course on outcome tests that will be useful in designing future clinical trials.

NIH supports basic, translational, and clinical research on SBMA through both extramural and intramural research programs. Several extramural grants are investigating the molecular steps by which the gene defects lead to disease and testing targets for intervention to halt the disease in animal models. Among the funded grants is a project in the NINDS Cooperative Program for Translational Research that is designed to carry out all of the drug development studies necessary to bring an oral drug for SBMA to readiness for human trials. This project is projected to reach its goal, if successful, in about four years. Other therapeutic strategies are at various stages of preclinical development. NINDS is prepared to fund meritorious proposals for clinical trials as therapies reach readiness for testing, including the opportunity to engage NeuroNext, a new NINDS clinical network at 25 sites throughout the U.S. that is designed to expedite early phase clinical testing of novel therapies. The NINDS Intramural Research Program also continues to be a leader in SBMA research. An intramural clinical trial is currently testing whether an exercise program can improve strength, function, or quality of life in people with SBMA.

As research on neurological diseases advances, the relationships among diseases are becoming increasingly apparent. SBMA was the first disease found with a type of gene defect called a triplet repeat expansion, that is, an abnormal repetition of a three letter sequence of the gene code. At least 9 diseases are now known to share the same repeat in different genes, and other triple repeat mutations cause several other diseases. More broadly, the gene defect in SBMA causes certain proteins to aggregate in an abnormal way, which contributes to the disease progress. Abnormal protein aggregation is similarly implicated in Alzheimer's, Parkinson's, Huntington's, ALS, and several other neurological disorders, both common and rare, and both inherited and not. Other commonality among diseases also illustrate how research on a single neurological disorder both informs and is informed by research on others. For example, certain naturally occurring growth factors in brain, such as Insulin-like Growth Factor (IGF), show promise as therapies for several diseases, and disruption of cells' energy production machinery (the mitochondria) is a common factor in many disorders. Research on rare disorders, including SBMA, may well have benefits for people beyond those directly affected. For this reason, as well as the impact of these diseases on patients and families, NIH places a high priority on rare disease research.

Questions for the Record
From Congresswomen Lummis

1) I would appreciate clarification on certain National Institutes of Health (NIH) research projects that appear duplicative of research occurring at other federal agencies. Given the strain of our budget limitations on precious biomedical research dollars, seemingly duplicative research should be scrutinized in order to avoid unnecessary overlap.

Health Economics Research

The Agency for Healthcare Research and Quality's (AHRQ) mission is to improve the quality, effectiveness and efficiency of the healthcare system. The Administration is requesting $409 million for FY13.

The new health care law created the Patient-Centered Outcomes Research Institute (PCORI) at the Center for Medicare and Medicaid Services (CMS). It is a nonprofit corporation "to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions." The FY13 budget proposes to release $78 million to PCORI from a taxpayer-financed trust fund established by the new health care law.

In addition, the NIH's "common fund" is home to a "Health Economics program" that granted 21 research grants for FY2011. The awards deal with the "economics of prevention," "market dynamics for long-term care insurance," integrating "comparative effectiveness" research into clinical practice, and examining the "economics of healthcare delivery."

Since we already have an entire agency devoted to health economics research at AHRQ, in addition to the new health law's support for health economics research at PCORI, please explain why the NIH is diverting basic biomedical research dollars towards duplicative research. Please also provide a breakdown of all such health economics research occurring at the NIH, as well as the portions of the NIH's FY13 budget proposal that are intended to support health economics research moving forward.

Answer: NIH is working with AHRQ and other agencies to collaborate on this critical issue to ensure that it does not conflict with their efforts and missions. The NIH's mission is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability." We initiated this Common Fund program in Health Economics as a way to measure the success of the translation of the benefits of our research into enhanced health of the US population. This is a complementary approach to that pursued by other HHS agencies.

Breakdown of Health Economics Research at the NIH

There is no specific program in health economics beyond the Common Fund program. Most institutes have as part of their portfolio in disease prevention, long-term care for chronic diseases, behavioral sciences relevant to health, or community-level health interventions, grants that use the methods and models of health economics.

Below are the specific amounts awarded or budgeted for the Common Fund Health Economics program.

	FY11 # Awards	FY11 Actual	FY12 Estimate	FY13 Estimate
Common Fund Health Economics (CFHE) Existing Awards	21	$5,401,418	$4,725,606	$1,238,775
Budget for Additional CFHE Awards	0	$0	$3,600,000	$11,300,000
Budget for CFHE Contract	0	$0	$1,500,000	$450,000
Total	21	$5,401,418	$9,825,606	$12,988,775

Bisphenol A (BPA) Research

The National Institute for Environmental Health Sciences (NIEHS) grants databases contain dozens of studies costing tens of millions of dollars that either focus on or mention the chemical BPA. At the same time, the Food and Drug Administration's (FDA) has an ongoing research program focused specifically on BPA because of public concern over its use in numerous consumer products. These studies are intended to provide a scientific basis for the FDA to reach sound conclusions on the safety of BPA-containing products.

In light of FDA's ongoing work on BPA in furtherance of consumer safety, why has the NIEHS also decided to spend a considerable amount of tax dollars on BPA research projects? Is there redundancy and overlap that might exist between the NIEHS's BPA funding and the FDA's ongoing efforts? Has the NIEHS taken any steps to ensure that current and future NIEHS-supported BPA research will contribute to, and not duplicate, the FDA's work?

Answer: The current portfolio of NIEHS funded work on BPA is part of a coordinated effort between FDA, NIEHS, and academic investigators to understand potential risks of BPA from lifetime exposure to BPA, including exposure in utero, and specifically designed to address persisting questions about the low-dose health effects of BPA. Much of the NIEHS-supported research has been, and continues to be, based on reports from a number of meetings of NIEHS and National Toxicology Program (NTP) staff, FDA staff, and NIEHS-supported researchers, conducted between 2007 and 2010. From these reports, it was evident that data gaps existed and that to effectively inform risk assessments and policy decisions, NIEHS needed to make more targeted research investments to elucidate the health effects of BPA. The current suite of research investments was created by NIEHS leadership in response to research needs arising from discussions with the FDA.

BPA-related research has included extramural efforts (including an ARRA "Grand Opportunity" and much investigator-initiated research) and a "core" study supported by NTP and conducted according to FDA regulatory guidelines by FDA staff at FDA's National Center for Toxicological Research (NCTR). This study includes a consortium of additional investigative academic research to address specific research needs.

There is no overlap or redundancy between NIEHS's funding and FDA's ongoing efforts in the area of BPA. NIEHS and FDA efforts to collaborate closely assure that our efforts are complementary. The core project, while being led and conducted by FDA staff, is coordinated by and under the auspices of the NTP (which is headquartered at NIEHS) and is funded almost completely by NIEHS under an interagency agreement between NIEHS and FDA. The additional investigational studies using biological samples from this study are being carried out by academic investigators supported by NIEHS grant funds. To ensure that current and future NIEHS-supported BPA research will contribute to, and not duplicate, the FDA's work, the whole consortium is managed by a steering committee comprised of NIEHS and FDA staff and academic investigators with advisory members present from the FDA regulatory centers to ensure that the data generated under the consortium is informative for risk assessment.

Questions for the Record
From Congresswomen Roybal-Allard

Pancreatic Cancer:

The "Emerging Areas of Focus" section of the NCI FY 2011 Action Plan for pancreatic cancer research outlines new research opportunities pertaining to pancreatic cancer.

Question:

1. **How many of the projects in the "Emerging Areas of Focus" section of the FY 2011 Action Plan have been initiated and what is the status of these projects to date?**

In FY 2011, 17 newly competing grant proposals and 59 grant renewals focusing exclusively on pancreatic cancer were funded after falling within what NCI calls the "zone of uncertainty."

Answer: The NCI FY 2011 Action Plan on pancreatic cancer research described projects and initiatives that NCI committed to support in FY 2011, and also identified a series of "emerging areas of focus" for pancreatic cancer research that relate to (1) collaboration and science planning; (2) leveraging existing resources to address gaps; (3) exploring potential new initiatives; and (4) identifying opportunities for advocacy groups and the pharmaceutical industry to take concrete actions to help advance the pancreatic cancer research field. In FY 2011, NCI funded 147 new grants and grant renewals focused exclusively on pancreatic cancer and many more projects partially focused on pancreatic cancer. All of these projects fall into at least one of these "emerging areas of focus" categories. Pancreatic cancer is a high priority for the NCI, and grant applications focused in this area that are reviewed by NCI's scientific leadership receive additional consideration.

Examples of ongoing projects in emerging areas of focus include:

- A collaborative National Cancer Institute (NCI) and National Institute of Digestive and Kidney Diseases (NIDDK) effort to examine the relationships among diabetes, elevated insulin levels in blood, and obesity in pancreatic cancer. These studies have already provided key insights about the risk of high body mass index and increased risk of developing pancreatic cancer, and several additional studies are underway to explore the role of these risk factors in pancreatic cancer.
- An NCI-Lustgarten Foundation collaboration for the Cancer of Pancreas Screening Study (CAPS 3) is an international effort involving 10 countries with the goal of screening high-risk individuals with inherited genetic mutations associated with pancreatic cancer. The researchers hope the study will begin to reveal new ways to detect the earliest signs of pancreatic tumors, and ways to distinguish nonthreatening cysts from those that might turn into cancer.
- Molecular imaging studies for detection and diagnosis of pancreatic cancer such as an ongoing study from NCI's Early Detection Research Network focus on identifying biomarkers to predict the malignant potential of pancreatic cystic lesions. The objective is to create a reference set of well-characterized cystic fluid and serum/plasma specimens obtained from patients with pancreatic cysts that could serve as a reference set for the development and evaluation of biomarkers that predict the malignant potential of pancreatic cystic lesions.

- NCI has established pancreatic cancer as a priority for the NCI Small Business Innovation Research (SBIR) Program, and has issued a funding opportunity announcement for proposals to develop new or improved application(s) of nanotechnology-based therapeutics and/or in vivo diagnostics. Currently funded projects are developing an imaging agent and a detection system for labeling and real-time detection of residual tumor cells from the tumor bed after gross tumor resection.
- To understand the root causes of pancreatic cancer, the NCI is supporting the development of a rapid autopsy program. Patients who died despite aggressive treatment had previously given permission to allow investigators to study their tumors, cells, and genes to make advances against pancreas cancer. More than 80 rapid autopsies have already been done, allowing investigators to look for genetic differences in pancreas cancer.
- NCI's new Provocative Questions Program is asking the question "can tumors be detected when they are two to three orders of magnitude smaller than those currently detected with in vivo imaging modalities?" If it were possible to detect very small clusters of pancreatic cancer cells in patients, it would dramatically improve our ability to detect pancreatic cancer early and would expand the treatment options for patients.
- NCI has been working with a group of pancreatic cancer advocacy organizations, including the Pancreatic Cancer Action Network, Lustgarten Foundation, and the National Pancreas Foundation to develop a collaborative funding model for pancreatic cancer research. This model would allow grant applications to be passed from one organization to another for supplemental funding if they are determined to be meritorious by NCI but are unfunded.

Questions:

1. **How do these figures compare to grants for other cancer types in the "zone of uncertainty" and what is the difference in overall funding levels?**

2. **What criteria are used to determine whether or not a proposal in the "zone of uncertainty" receives funding?**

Answer: NCI has been paying special attention to grants that might in the past have been unfunded because they fell below what used to be considered a "payline," a percentile score derived from the results of peer review. Beginning in FY 2011, NCI scientific program leaders have been performing additional evaluations of grant applications to ensure a balanced grant portfolio and to recognize the value of research proposals that are highly original or address important scientific priorities, such as research on pancreatic cancer, even though they might not have received percentile scores that fall within a pre-determined payline. With the new process, applications that score exceptionally well, falling within the top 7th percentile, almost always received funding. Applications that score well, but outside of the 7th percentile, are placed in a "zone of uncertainty" and are further evaluated by the NCI's scientific program staff and leadership before a decision is made about recommending them for funding. A more detailed explanation of this process and overall funding patterns is available on NCI's website at: https://deaissl.nci.nih.gov/roller/ncidea/entry/funding_patterns

Of the applications that were focused exclusively on pancreatic cancer and were funded in FY 2011, more than a third were selected as a result of this programmatic review, rather than on the basis of receiving exceptionally high scores. While this number is similar to those for grants focused on other cancer types, it is not possible to make simple comparisons because of several complicating factors. First, the numbers of grant applications in most categories for one year

are relatively small. More importantly, several factors, including originality, potential for reward, and scientific rigor, in addition to cancer type, are taken into consideration. Furthermore, the existing classification scheme does not adequately reflect the potential importance of many grant proposals to the problems posed by pancreatic cancer. For instance, studies that address genetic, molecular, and biological features of various kinds of cancers are often directly applicable to pancreatic cancer. Finally, this analysis of research project grants does not include several other approaches that the NCI is taking towards pancreatic cancer, including clinical trials (through the Cooperative Clinical Trials Groups), genetic studies (through The Cancer Genome Atlas project), and support through the NCI-designated cancer centers program.

A full list of FY2011 research funding by cancer type is available on the NCI's website at http://fundedresearch.cancer.gov/search/funded?action=full&fy=PUB2011&type=site.

Questions for the Record
From Congressmen Jackson

NIMHD

The law that established the now National Institute on Minority Health and Health Disparities (NIMHD) provides the statutory authority for the director of the NIMHD to work with other NIH institutes and the NIH director to develop, implement, and periodically update a strategic plan for the organization of NIH-wide resources to study topics related to reducing minority health disparities.

What is the status of the release of the most recent strategic plan, and what are the results of the previous strategic plan?

Answer:

The most recent NIH Health Disparities Strategic Plan and Budget is available on the NIMHD website, at www.nimhd.nih.gov. The NIH Institutes and Centers implemented new programs and initiatives, or expanded existing ones consistent with the goals and objectives of the previous strategic plan. The increased investment in funding for health disparities from $2.5 billion in 2004 to $2.7 billion in 2010 is an indication of progress. There has also been increased focus on: a) establishing transdisciplinary networks to address health disparities, b) studying the social, economic, and environmental factors that impact health in health disparity communities; and c) integrating practice and policy approaches with science to examine factors that contribute to health disparities.

NCATS

The establishment of the National Center for Advancing Translational Sciences (NCATS) included the transfer of programmatic activities from the National Center for Research Resources to other NIH institutes. Among these transfers is the Research Centers in Minority Institutions (RCMI) program to the National Institute on Minority Health and Health Disparities.

Do these transfers include the appropriate level of internal NIH resources to effectively administer the programs at their new locations?

Answer: The transfer of the Research Centers in Minority Institutions (RCMI) program to NIMHD included sufficient funds to continue the important programmatic activities, as well as funds to support the required NIMHD administrative and fiscal oversight responsibilities for the RCMI Program. The purpose of the NIMHD RCMI Program is to expand the national capability for research in the biomedical and health sciences by providing grant support to minority institutions that offer doctorate degrees in the health professions or in a health-related discipline. The RCMI Program consists of four interconnected programmatic initiatives: 1) RCMI Centers, 2) RCMI Infrastructure for Clinical and Translational Research, 3) RCMI Translational Research Network, and 4) Clinical Research Education and Career Development Awards.

R01 GRANTS THROUGH NIH

Last year the NIH and the Journal *Science* reported that the success rate for African American scientists receiving R01 grant support from NIH was only about one-half that of white applicants. It is my understanding that a blue ribbon panel has been appointed to review these findings and make recommendations to improve the success rate of African American researchers.

The NIH is to be applauded for this action. Please tell the committee more about this national problem. It is my further understanding that several prominent African American scientific leaders have asked for an opportunity to meet with you to discuss potential solutions.

Will you be giving these leaders an opportunity to meet with you to discuss this national concern?

What other opportunities for input will be offered during the deliberations of the blue ribbon panel?

Answer: "Race, Ethnicity and NIH Research Awards" by Dr. Donna Ginther et al., a NIH-commissioned study published in the August 2011 edition of Science, detailed a stark disparity in success rates between White applicants and Underrepresented Minority (URM) applicants. The disparity was most pronounced between Black investigators and White investigators - 10 percentage points after controlling for a variety of observable factors.

The NIH mission can only be achieved if the best and brightest biomedical researchers, regardless of race, ethnicity, disability, socioeconomic background, or gender, are recruited and retained in our workforce. However, the findings of Ginther et al. and others indicate that NIH's current approaches and those of other stakeholders have not gone far enough to facilitate and encourage the recruitment and advancement of underrepresented minorities in biomedical research. This is unacceptable.

Dr. Collins charged the NIH Advisory Committee to the Director to establish a Working Group on Diversity in the Biomedical Research Workforce to provide concrete recommendations to the NIH Director on ways to improve the retention of underrepresented minorities, persons with disabilities, and persons from disadvantaged backgrounds through the critical transition points in the research career pipeline. The Working Group will be providing its recommendations at the June 2012 meeting of the Advisory Committee to the Director.

The Working Group has met with many stakeholders, including during a public meeting held at the NIH on Tuesday, February 14, 2012. The summary and transcript from that meeting can be found at http://acd.od.nih.gov/dbr.htm. The Working Group has also received numerous recommendations from individuals, associations, and institutions, and will take all of them into account when formulating their final recommendations. In addition, the NIH Director and NIH Deputy Director have met with Drs. Louis Sullivan and Donald Wilson to discuss their recommendation for a mentoring program and the NIH Deputy Director and Dr. John Wilson, Director of the White House Initiative on Historically Black Colleges and Universities (HBCU)s, held a meeting with representatives from a number of HBCUs.

PEDIATRIC LOW GRADE ASTROCYTOMA

Pediatric low grade astrocytoma (PLGA) is a slow growing children's brain cancer. Current treatments for PLGA brain cancer include surgery, chemotherapy, and radiation on the brain. In young children battling PLGA brain cancer, these therapies on the brain are invasive, highly toxic, and cause devastating side effects as well as substantial morbidity. Those children who survive battles with PLGA are often left with disabled minds and bodies as a result of their treatments.

I am encouraged by a statement in the NIH budget request which says, "Major advances in understanding the biology of PLGA have been achieved over the past five years, and because of these advances, clinical research teams are now poised to translate these findings into new therapeutic options."

What treatment options are on the horizon for children battling PLGA? What more needs to be done to advance this research?

Answer: The recent advances you reference are already leading to research initiatives to explore less toxic treatment options for children with PLGA. The most significant of the research advances, supported in part by the NCI, is the recognition that the vast majority of pediatric pilocytic astrocytomas (the most common PLGA) have genomic alterations involving a gene called BRAF, and preclinical models that will allow identification of promising candidate treatments are being developed. The BRAF mutations are of two primary types: one type is identical to the BRAF mutation (BRAF V600E) that occurs in a high percentage of patients with the skin cancer melanoma, while the other type of alteration appears to be unique to pilocytic astrocytomas. NCI-supported researchers at the Children's Hospital of Philadelphia, along with other research teams, have shown that additional types of PLGA (e.g., ganglioglioma and pleomorphic xanthoastrocytoma) also have the BRAF V600E mutation. The PLGA-specific alteration in BRAF is not susceptible to the inhibitors used against mutant BRAF in melanoma, so an alternative approach has been taken, based on a molecular understanding of the BRAF pathway.

Building upon this work, the NCI-supported Pediatric Preclinical Testing Program has developed a model for a subtype of PLGA with the BRAF V600E mutation, and identified a targeted agent called selumetinib that is effective against the model. Selumetinib inhibits the activity of a protein called MEK and blocks cellular signaling downstream of BRAF, leading to inhibition of the cancer promoting effects of activated BRAF in astrocytoma cells. Based in part on these preclinical results, the NCI-supported Pediatric Brain Tumor Consortium is currently conducting

a Phase I trial of selumetinib in children with PLGA who have progressed after receiving radiation therapy. Other research teams have developed preclinical models for this same BRAF V600E subtype of PLGA and are using these models to identify novel agents effective against this disease. In addition, preclinical models of a type of PLGA based on alterations in the NF1 gene (the gene that causes neurofibromatosis 1) have been used to identify new therapeutic targets for PLGAs with NF1 alterations. In other efforts focused on neurofibromatosis-associated PLGA, NCI researchers screened thousands of existing drugs and new compounds isolated from plants and marine life for potential therapeutic activity for PLGA.

Additionally, in March 2011, the NCI awarded $7.5 million to the PLGA Program at the Dana-Farber Cancer Institute. The long-term goal of this five year program is to improve the standard of care for PLGA. Towards this end, investigators aim to improve the understanding of astrocytoma biology and develop new diagnostic, prognostic and therapeutic tools for these tumors.

The NCI-supported Pediatric Brain Tumor Consortium recently completed a Phase I trial of the agent, lenalidomide (an immunomodulator), in children with recurrent, refractory and progressive central nervous system tumors, including PLGAs. A notable finding was that the children with PLGAs had a 67% 12-month progression-free survival, a number that is rarely observed in a Phase I setting and which compares favorably with current therapy. This prompted the NCI-supported Children's Oncology Group (COG) to develop a Phase II trial of lenalidomide in children with these tumor types, to further study the potential efficacy of this agent. This study will be open at more than 150 institutions across the country and is undergoing institutional review board approval now (April 2012).

The COG also completed a Phase III study comparing two combination chemotherapy regimens for PLGA, and completed enrollment for a Phase II study evaluating the efficacy and toxicity of specialized radiation therapy that delivers radiation directly to the tumor and reduces radiation to normal tissue. Final results for both studies are pending. NCI is also conducting and supporting research on optimal imaging methods for assessment and monitoring of PLGA disease status, and the Pediatric Neuro-Oncology Section of NCI's Pediatric Oncology Branch is developing a research study evaluating inflammatory and immune-mediated features in children who develop PLGAs to determine if these factors play a role in the cause or origin of the tumors.

Other NIH Institutes support research on PLGA. For example, the National Institute of Neurological Disorders and Stroke (NINDS) supports studies to carefully dissect the molecular and cellular underpinnings of PLGA, including funding the development of a new BRAF mouse model to be used for pre-clinical therapeutic testing. These studies, in conjunction with discoveries from the NIH Cancer Genome Atlas (TCGA), which analyzes the complete genomes of various cancer types, should enable scientists to better identify different subtypes of astrocytoma. The NINDS supports several therapeutic development initiatives, including a translational research program and the trans-NIH Neurotherapeutics Grand Challenge, which encourage proposals for the development of novel drugs for all neurological disorders, including PLGA.

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is supporting the development of multifunctional drug and gene delivery systems. Such systems can target therapies to particular cells and intracellular compartments in the affected tissue, including

brain, and can monitor drug delivery and therapeutic efficacy using advanced imaging and/or sensing technologies. This approach has potential to reduce treatment toxicity while increasing efficacy.

Future advances in understanding the genomic alterations of PLGAs are anticipated, as genome sequencing of PLGAs is being undertaken by a team of German pediatric brain tumor researchers through the International Cancer Genome Consortium (ICGC), of which NCI is also a partner. The ICGC collaborative effort allows member institutions to prioritize research efforts and avoid duplication. For example, while German researchers are taking the lead in collecting and analyzing PLGA tumor tissue samples, the NIH's TCGA is taking the lead on collection and analysis of other brain cancer types. TCGA will also be moving toward collecting available tissue samples from pediatric and adolescent astrocytomas such as PLGA to further advance research of this pediatric cancer.

ADVANCEMENTS IN TREATMENT AND PREVENTION OF DIABETES

According to the CDC, the percentage of adults in Illinois with diagnosed Diabetes is now at 8.2 percent – up from 6.3 percent just ten years ago. This means that more than 827,000 adults in Illinois have been diagnosed with diabetes, and each year more than 2,700 residents die from the disease. Many more suffer from complications such as heart disease, vision loss and amputations. The burden of diabetes is even higher among minority populations, such as African Americans, Hispanics/Latinos, American Indians, Asian Americans and Pacific Islanders.

Are there new treatments for diabetes on the horizon?

Are there new real world, practical prevention strategies being developed and tested that can help stem the rising tide?

Answer: The NIH and NIDDK are committed to combating diabetes, and reducing the serious disparities that exist in diabetes prevalence and outcomes. Importantly, although both an aging population and rising obesity rates are leading to more new cases of diabetes, overall prevalence of diabetes in the population is also increasing because diabetes care has greatly improved, in part as a result of NIH research, which is helping people with diabetes live longer, healthier lives. For example, the NIH supported Diabetes Control and Complications Trial and United Kingdom Prospective Diabetes Study showed that improving glucose control helps reduce diabetes complications. New treatment options now on the market that stem from NIH research include GLP-1 analogs (e.g., exenatide) and DPP-4 inhibitors (e.g., sitagliptin). These new therapies, as well as improved insulin formulations and delivery devices are helping people better control diabetes today than has been possible in the past.

Current NIH research is investigating the potential for a generic pain medication, salsalate, to help improve blood glucose control in people with the disease. The NIDDK's Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study is looking at how best to treat the emerging problem of pediatric type 2 diabetes, which disproportionately affects minority children. The Action for Health in Diabetes (Look AHEAD) clinical trial is testing a lifestyle intervention designed to reduce weight for benefit in improving blood glucose control and preventing complications in people with diabetes. Other ongoing NIDDK-supported research

includes efforts to understand how bariatric surgery may lead to remission of type 2 diabetes that occurs even before weight loss. Understanding the mechanisms underlying this may lead to new approaches to therapy.

The NIH's landmark Diabetes Prevention Program Clinical Trial proved that an intensive lifestyle intervention reduced rates of diabetes incidence by 58 percent in an at-risk population. The intervention was effective in all racial/ethnic groups tested (including African Americans, Hispanics/Latinos, American Indians, and Asian Americans, as well as whites), and was particularly effective for people 60 years of age or older. A follow-on study shows the approach remains quite effective for at least a decade.

Translational research seeking to reduce the cost of the lifestyle intervention has been a key NIDDK program goal. One general approach that is producing very encouraging results in a variety of ongoing studies is to deliver the intervention in group sessions by trained providers who are not physicians. From exciting preliminary results from these NIDDK supported studies, the CDC developed the "National DPP" to produce a cadre of credentialed providers who can give the group intervention, now being offered at over 50 YMCA branches around the country. (See http://www.ymca.net/diabetes-prevention/participating-ys.html). Under law, the Centers for Medicare and Medicaid Services are unable to reimburse for such prevention services; however, some private insurers, such as UnitedHealth Group, have begun to cover such care.

The DPP also found that the safe, well-tolerated, inexpensive, generic diabetes drug metformin was also quite effective for prevention of diabetes, particularly in younger participants, and women with a history of gestational diabetes, who otherwise develop type 2 diabetes at particularly high rates. In addition, recent research has suggested the possibility that vitamin D may have promise in helping reduce type 2 diabetes risk, and NIDDK is supporting the planning of a study to test the approach.

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